INTRA-UTERINE CONTRACEPTION - SUMMARY

The two main methods of contraception currently in general use are the mechanical barriers and oral hormones. Both demand standards of intelligence and care not present in all patients, and there is a need to develop other safe and effective methods which are free from these disadvantages. Intra-uterine devices have some potential advantages over other methods but the modern types of device were only introduced into the United Kingdom during the last few years, and their merits and demerits have not so far been adequately studied. In the present investigation the field of application of these devices, their efficacy, and the complications associated with their use have been assessed in more than 500 women. Each of the participants in the survey attended one of three places in London: a family planning association clinic which drew its patients from a wide area, or as private patients in a West End practice, or at a clinic at the Royal Free Hospital situated in one of the poorer areas in London, where there is a large number of immigrants. IUDs were thus assessed in a wide variety of patients who came from all social classes.

The main groups were nulliparous women who wished to postpone starting a family; parous women who were sufficiently intelligent and methodical to use other methods of contraception but who found such methods unacceptable or for whom such methods were contraindicated on medical grounds; parous women whose poor intelligence and motivation render them incapable of using other contraceptive methods. For this

third group further pregnancies were undesirable either on socio-economi or medical grounds.

The follow-up of the patients showed that intra-uterine devices provide a high degree of, but not complete, efficacy. Their main disadvantages were found to be a tendency on the part of some patients to expel the device, and the frequent occurrence of menorrhagia. Potential hazards were the occurrence of pelvic infection and perforatio of the uterus. IUDs were found to be unsuitable for nulliparae, but offered a useful alternative for parous women who found other methods of contraception unacceptable. For parous women who are insufficiently intelligent or methodical to use other methods of contraception, the IUD is the method of choice.

INTRA-UTERINE CONTRACEPTION

A thesis submitted for the degree of

Doctor of Medicine of the University of Glasgow

by

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"I would suggest that it is time to consider a fifth Freedom - freedom from the tyranny of excessive fertility"

Sir Dugald Baird, M.D., F.R.C.O.G., in the Sandoz Foundation Lecture given at University College Hospital, London, on 25 May, 1965.

"Planned parenthood strengthens family life; lack of planning, often due to ignorance of effective methods of contraception, may lead to mental disharmony, ill health and social breakdown and in some cases even to criminal abortion and death"

Minister of Health, in his Circular to Local Authorities on 17 February, 1966.

CONTENTS

INTRODUCTION

Contraception has been practised from very early times, certainly long before the Christian Era. There is a reference in the Bible (Genesis, chapter 38, verses 9-10) where Onan, who practised coitus interruptus, was slain by the Lord for his sin. In antiquity anticonceptional methods were widely known and the vaginal sponge, chemical pessaries and other less scientific methods were described in the writing of the ancient Egyptians, Greeks and Romans. During the Middle Ages, contraception seems to have been uncommon. Later the sheath, made of linen or of the intestinal membrane of animals, was described by Fallopius (1564) but only as a preventive against venereal disease. Casanova (1725-1798) in his mémoires made frequent mention of the sheath for contraceptive purposes. He describes it as a 'preservative that the English have invented to put the fair sex under shelter from all fear'.

All these early references refer to the practice of contraception for personal convenience. The social necessity for contraception was not realised until the end of the eighteenth century, a time of growing industrialization and urbanization. Bentham (1797) recommended the use of contraceptive methods for reduction in the poor rates. Malthus (1798) pointed out the dangers attendant on the rapid growth of population, but advised later marriage as a method of reducing the birth rate.

Place (1778-1854) was the founder of the modern birth control movement and attempted to educate the masses by distributing handbills which advertised the disadvantages of too large a family and described simple contraceptive methods.

In the 1880s the discovery of the vulcanization of rubber led to the mass production of sheaths which remain one of the most widely used contraceptives. At about the same time the vaginal diaphragm was invented by Mensinga. The use of contraceptives was confined mainly to the privileged classes until 1921 when Marie Stopes opened her first birth control clinic for poor women in London. Since then the use of female methods of contraception has steadily increased. In 1961, oral contraceptives became available in this country and are now probably the most popular form of contraceptive for women. The newer types of intra-uterine devices were introduced in 1965.

Since the Second World War, the rapid and accelerating increase in the world's population, without appropriate increase in living space and food supplies, has become a matter for some alarm. It now seems likely that the world population will be doubled by the end of this century and will - if this state of affairs were to continue - double and redouble at ever-decreasing intervals. Even in England and Wales, at the present rate of progress, it is estimated that the number of births each year will increase from 863,000 in 1963-4 to 1,147,000 in the year 2000 (Baird, 1965). These and other considerations led to the

passing of the National Health Service (Family Planning) act of 1967, which gives local authorities in England and Wales the power - though not yet the duty - to provide advice on contraception to all who seek or need it. The Health Services and Public Health Act passed in July 1968 gives similar powers to local health authorities in Scotland.

The ideal contraceptive should satisfy certain requirements. It should be effective, it should be safe, and it should be cheap. If it is to be widely used it must be simple and aesthetic. Considerations of efficacy and economy apply with special force to the developing countries, where the need is most acute, and to those members of advanced communities where need is accentuated by high parity and poor socio-economic background.

Of the contraceptive methods now in common use, barrier methods such as sheaths and vaginal diaphragms satisfy some of these requirements. Oral contraceptives, while extremely effective, are not entirely trouble-free and their safety is now in some doubt. The newer types of intra-uterine devices (IUD) which have only recently been introduced on a wide scale, have some potential advantages over other methods but the advantages and disadvantages of the IUD have not yet been fully assessed. In making such an assessment it is essential to take into account the medical and social needs of individual patients, to examine them at regular intervals, and to include in the assessment sufficiently large numbers of patients. It is an advantage if the same doctor fits the device and makes the subsequent examinations.

In the investigation described below, an assessment has been made of 539 patients, each of whom was fitted with an intra-uterine device by the author. Almost all the patients were re-examined at least once after fitting and some were regularly re-examined for a period of up to three years. In the assessment an attempt has been made to answer two main questions. Have intra-uterine devices a place in contraceptive practice in the United Kingdom: if so, what are the indications and contra-indications to their use?

Special attention has been paid to the following aspects of these questions: the needs of various types and social classes of patients who seek contraceptive advice and the reason for the choice of an IUD; the problems and immediate complications of fitting IUDs of various types; the efficacy of the IUD in preventing pregnancy and the reasons for failure; the frequency with which the devices are expelled or removed; the complications associated with their use; and their general acceptability to the patient.

(The following references in this Introduction were all cited by Himes, N.E. (1936, reprinted 1963). Medical History of Contraception, New York, Gamut Press -

	page	
Onan	71	
Fallopius	187	(1564)
Casanova	195	(1725-1798)
Bentham	211	(1797)
Malthus	211	(1798)
Place	213	(1823)
Mensinga	211	(1882)
Stopes, Marie	258	(1921)

HISTORICAL REVIEW

It has long been known that a foreign body in the uterus will prevent pregnancy; for centuries Turkish and Arabian camel owners have inserted a small stone into the uterus to prevent conception while crossing the desert, (Southam, 1965). Hippocrates in his 'Diseases of Women' mentions the insertion of intra-uterine pessaries for gynaecological but not contraceptive reasons.

During the nineteenth century cervical stem pessaries made of metal or ivory were used by gynaecologists in the treatment of uterine displacements and dysmenorrhoea, and were found to have a contraceptive effect even if this was not their primary intention. Pust's pessary (1923) was designed as a contraceptive. It consisted of a ring of silkworm gut, placed in the uterine cavity with a thread through the cervical canal holding a glass bead over the cervix; its effect was thought to be due to the occlusion of the cervix rather than to the intra-uterine foreign body.

At the Sexual Reform Congress held in London in 1929, Grafenberg (1930) stressed the subjective reaction of women to contraceptive methods and said that many found those requiring deliberate preparation repugnant. He disapproved of the Pust pessary with its connection between the vagina and uterus as he felt that this might lead to infection of the uterine cavity. Grafenberg preferred a genuinely intra-uterine method and had made experiments with various devices, beginning with a silkworm gut pessary which was entirely intra-uterine. He next

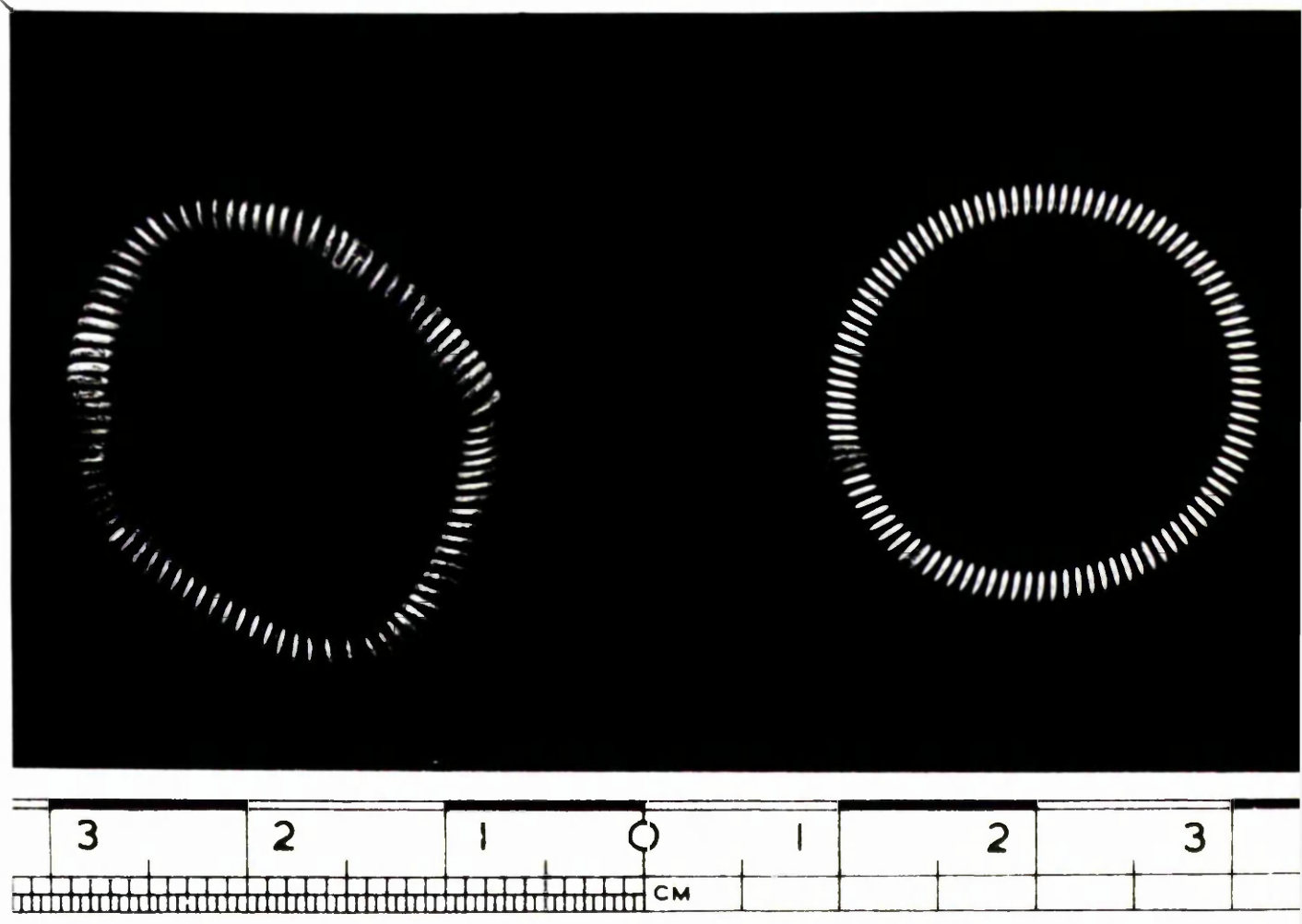

PLATE I

Silver Grafenberg ring Stainless steel ring

both removed after being in the uterus for one year. Note that the stainless steel ring is in much better condition than the silver ring.

produced a star-shaped bundle of six pieces of silkworm gut held together with silver wire, with the free ends knotted to avoid sharp projections. But these devices were so soft that they were often extruded by uterine contractions and he next tried a ring of silkworm gut held together with silver wire; this was not so easily expelled. Later he made the ring of coiled silver wire only and found that one with a diameter of 20 mm. was suitable for the majority of his patients: he also made larger silver rings with diameters of 25 and 30 mm. In later years two or more strands of silkworm gut were introduced into the hollow of the coil to hold it together should it break.

Grafenberg chose his patients with great care. He would not fit those with inflammation of the adnexa, infection of the vagina or cervix - especially gonorrhoea, or menorrhagia. He took a careful case history and made a thorough examination, stressing the importance of careful sterilization, and placing the ring so that its lower pole was completely within the uterine cavity. He advised that the ring should be fitted immediately after menstruation to ensure that the patient was not already pregnant. Grafenberg inserted his rings with a specially-designed instrument with a forked tip, without an anaesthetic but with full aseptic precautions and after dilatation of the cervix to 6 mm. His patients were examined after one week for any sign of infection and again after the first period. Any pain lasting for more than a few hours after insertion was regarded as abnormal. At first he removed and replaced the ring at yearly intervals, but later he left them in

place for indefinite periods, but examined his patients each year. For removal he designed an instrument ending in a slender hook.

His results were as follows:-

silkworm threads - expulsion in 8.2% (followed by pregnancy in 5.3%). Pregnant with pessary in situ 0.88%.

silkworm ring - expulsion 1.25% (followed by pregnancy in 0.41%). Pregnant with pessary in situ - nil.

silver ring - best results (figures not given).

(At the 7th International Birth Control Conference in 1930 he reported that of 600 patients fitted with silver rings only 1.6% had become pregnant and the expulsion rate was 0.7%).

Grafenberg was uncertain of the method of operation of these devices and wondered whether it might be due to some physico-chemical change in the uterine secretions. With Robert Meyer he found no evidence of chronic inflammation of the endometrium, although he had originally thought that this might be the mode of action. He did, however, observe that the premenstrual endometrium appeared to be more active than normal, resembling the pregravid state and regarded this activity as a hyper-decidual reaction to a foreign body.

At the same Congress, Lefeldt (1930) reported on 500 patients in whom he had used a silkworm gut ring with a thread extending into the vagina to facilitate removal. Only 3% of these patients became pregnant, but like Grafenberg he disliked the connection between the

vagina and uterus and later recommended the Grafenberg ring.

In other hands the use of these rings was less successful. Pregnancy was much more frequent, and some severe cases of pelvic inflammation were reported. Haire (1930)(1938) and Leunbach (1930) (1932) who were at first enthusiastic about the use of these rings reversed this opinion after further experience.

Most gynaecologists condemned this method of birth control, partly on theoretical grounds and partly because of unfavourable reports, and Grafenberg rings were ignored in textbooks of gynaecology or mentioned only with disfavour. With one exception (Halton et al. 1948) who used coils of silkworm gut, no reports of intra-uterine contraceptives were published for more than twenty years between 1934 and 1955.

At the 5th International Conference on Planned Parenthood held in Tokyo in 1955, Ota reported on his experience with the intra-uterine ring which he had used for over twenty years. His ring was a modification of the Grafenberg design. It consisted of an outer coil 23 mm. in diameter, in the centre of which was a small hollow capsule 8 mm. in diameter suspended by three radial springs. The rings were originally made of gold or gold-plated on silver and eventually of plastic. They were 85% effective in preventing pregnancy in the early months after insertion and 95% when patients became accustomed to them. At the same conference Suzuki & Yoshida (1955) reported on 700 cases where the same type of ring was used with an 83.6% contraceptive effectiveness; there were no complications. Despite these encouraging results the Japanese

experience made little immediate impact in the west.

In 1959 the editors of the American Journal of Obstetrics and Gynecology invited Oppenheimer of Israel to write an article on intra-uterine contraceptives since no American gynaecologist could be found to report on this subject. In their editorial they pointed out that Grafenberg had claimed both safety and contraceptive effectiveness but the reception of this method of birth control had been stormy from the outset. The editorial drew attention to the fact that at the 7th International Birth Control Conference in 1930 many gynaecologists were opposed to the method but not one of the opponents had had any experience of its use. On the other hand, Norman Haire of London who had had experience was staunch in its defence. Most opposition arose from unfortunate experiences with intra-uterine devices such as Fust's pessary, which had had extensions protruding through the cervix into the vagina. Opposition had won the day, especially in U.S.A. and the technique had disappeared. The editors were careful to point out that 'publication of this re-evaluation does not constitute official or personal endorsement on their parts of the Grafenberg ring.'

In his article, Oppenheimer (1959) reported that he had inserted the Grafenberg ring 1,016 times since 1930 and had found it far superior to other methods of contraception. The results were better than with soft rubber caps and it could be used when a cap was not liked or could not be fitted in women with prolapse or retroflexion. In his experience the ring had caused no illness and its use was not followed by sterility.

Like Grafenberg, he stressed the necessity of choosing suitable patients and of excluding those with any kind of infection by taking preliminary swabs from the cervix and urethra. He also excluded patients with menorrhagia. Oppenheimer's results were good, in that there was no case of inflammation or infection even in pre-antibiotic days. He thought that the probable reasons for the infection in earlier cases included insertion without proper aseptic precautions, insertion in cases of unrecognised or latent infection, subsequent infection with gonorrhoea and attempted illegal abortion after failure of contraception. Oppenheimer did not advise the use of rings in nulliparous patients as the rings were often rejected and he recommended that the ring should be removed and re-inserted at yearly intervals. Failure of contraception occurred twice in 150 patients with silver rings (1.3%), and in another series twenty times in 866 patients with silver rings or silkworm gut rings (2.4%) No cases of cancer (cervix or corpus) occurred in his series although some patients had worn the ring from 10-20 years. Curettage was carried out after removal in 10 cases; no inflammatory changes were found and the tissue that had formed on the ring showed only a foreign-body reaction. No foetal malformation or miscarriage occurred in the patients who became pregnant with the ring in situ.

In the same year Ishihama (1959) reported on the use of Ota rings in Japan. There were 623 cases in which the metal ring had been used and 350 with the polyethylene ring. With the former 5.2% had to be removed because of serious disturbance and 1.3% became pregnant. With

the plastic ring 1.7% became pregnant but the removal rate was not reported. He thought that his failures were either due to insertion of the ring after induced abortion when the uterine cavity was too large and placement was too low, or to unnoticed expulsion of the ring. He had no cases of perforation of the uterus and the incidence of pelvic inflammatory disease was only 0.4%. In the five cases in which the ring was removed, pregnancy occurred within 2-3 months. The endometrium was examined histologically in all cases and no abnormality was noted. There was only one case of carcinoma of the cervix and there was no histological relationship between this and the ring in the uterus.

In England Margaret Jackson (1962) began, in 1939, to use the silver Grafenberg ring in family planning clinics for highly fertile 'problem patients'. These women had tried other methods such as the cap or sheath and chemical spermicide and had failed at least once; they already had an average of six pregnancies. The ring appealed to Margaret Jackson as the only method, apart from sterilization, where responsibility for control could be removed from the patient. She stressed the need for choosing patients with normal pelvic organs and pointed out that normality is likely in women who are highly fertile. She found that these patients were not difficult to fit after dilatation of the cervix up to size 7 Hegar, and usually used the 25 mm. ring. She advised removal and replacement of the ring at yearly intervals since she considered that the ring tended to become embedded. There were 192 patients in her series and the pregnancy rate was 4.1 per

hundred cases. Margaret Jackson began to use Lippes loops in 1962 and found these easier to insert than the Grafenberg ring. Moreover, there was less bleeding and pain after fitting. (Jackson, 1963).

In 1962, Hall & Stone reported the use of a stainless steel Grafenberg ring, 22 mm. in diameter. They considered that stainless steel - an inert substance - might be an improvement on the silver ring which is affected by tissue fluids and tends to disintegrate and to become embedded in foreign body granuloma. (Carleton & Phelps, 1933). Hall & Stone reported on 128 patients fitted between 1949-60. The reasons for choosing this method in their cases were: spacing of births (25 cases); temporary sterilization for medical or psychiatric reasons (13 cases); where a diaphragm could not be fitted (27 cases); and, where a cap was not liked (13 cases).

The ring was inserted with the patient in the lithotomy position, (Grafenberg employed the left lateral position) after dilatation of the cervix to 7-9 Hegar and was left in position for an indefinite period. One hundred and twenty eight patients were observed over 527 years of use. The ring was expelled in 6 cases, there were 6 unplanned pregnancies (one with the ring still in situ) and one ectopic pregnancy (also with the ring in the uterus) a failure rate of 0.9 per hundred woman-years of use. There were no cases of pelvic infection or other serious side effects. The ring was removed thirteen times from patients who wished to become pregnant; after removal conception followed readily.

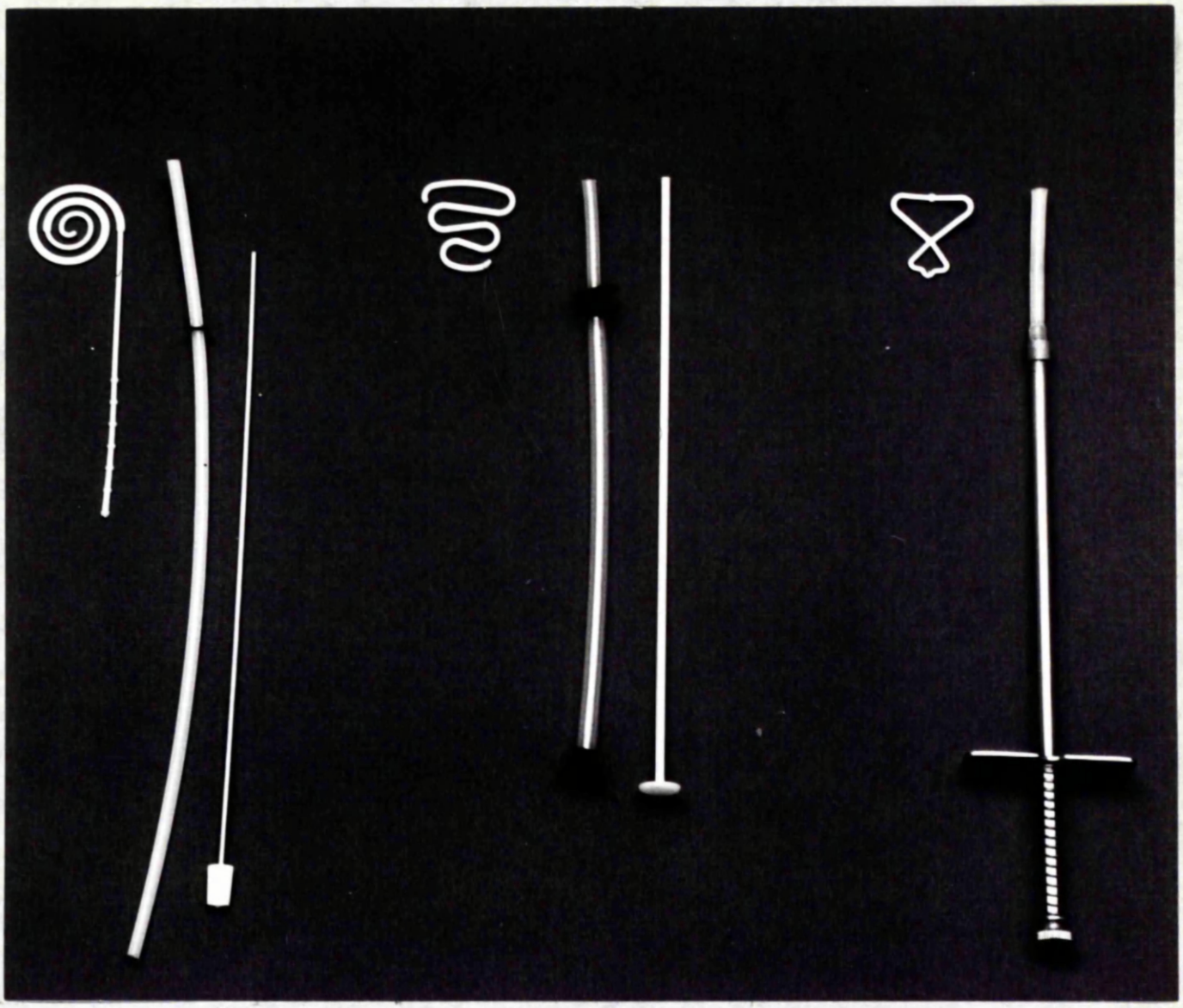

PLATE II

Margulies spiral and introducer

Lippes loop and introducer

Birnberg bow and introducer

In April 1962, the Population Council called a conference on Intra-Uterine Contraceptive Devices, to assess the effectiveness and safety of these devices and the possibility of their widespread use. It was considered that there was an urgent need to find some method of restraining population growth, especially in the Far East, where the more usual Western methods (birth control for the individual) were unsuitable. Guttmacher (1963) defined the purpose of the conference as being 'to find out scientifically, honestly and in depth the value of modern intra-uterine contraception'. He considered that if these devices were found to be as valuable as they seemed to be on superficial investigation, the conference should rehabilitate this method in the eyes of the medical profession throughout the world.

At this conference the intra-uterine devices (IUDs) made of moulded polyethylene (containing 20% barium sulphate to make them radio-opaque) were first described.

At the conference Margulies (1962) reported that in 1959 he had begun to experiment with polyethylene tubes filled with radio-opaque material, he had broken from the concept of the ring and designed an IUD in the form of an 'S', next as a double 'S' and finally as a spiral in moulded plastic containing barium sulphate. He inserted the first spiral in September 1960, and in 1961 he made the spiral with a tail to project from the cervix. This enabled the patient to check it and facilitate removal.

Lippes (1962) described his experiences with the Ota ring, which he had found satisfactory, although the device was difficult to remove. With this in mind he attached a suture to project through the cervix to the ring and found that in 171 cases there was no evidence of pelvic infection. In 18 of these cases the suture was drawn up into the uterine cavity. He thought that this was due to rotation of the ring inside the uterus and set out to devise an IUD which would fill the uterine cavity in a stable manner and not rotate. He finally designed the double S loop (known by his name) in the shape of the uterine cavity in moulded polyethylene with tails of 0000 polyethylene filament. The first loop (loop 1 A, 25 mm. in diameter) was introduced in November 1961 and the larger loop (loop 2 D, 30 mm. in diameter) in November 1963. Loop 3 C (30 mm.) and loop 4 B (27.5 mm.) were introduced in 1964, and were made more resilient by flattening the polyethylene rod in the curves of the double S.

Birnberg (1964) described a new device, in the shape of a double triangle, which was placed in the uterus and had no cervical appendage. This device was designed to resist ejection because the force of uterine contraction could compress only one triangle at a time. Although the lower triangle was pushed against the internal os by a uterine contraction, elastic recoil of the plastic would draw the triangle back into the uterus as soon as the contraction terminated. Birnberg's design was known as the bow 3. He later devised a larger and

thicker bow - the bow 5 - and then the bow 6, intermediate in size between the bow 3 and the bow 5.

In June 1963 the Population Council in U.S.A. began a co-operative statistical programme for the evaluation of IUDs. The uniform collection and processing of data for their analysis was done by Tietze (1965) for the National Committee on Maternal Health. The 6th Progress Report (1965) is based on the data from 33 investigators who submitted individual case records for 22,403 women, with an aggregate of experience of 261,689 woman-months between July 1963 and December 1965. Frequent references to this extensive analysis will be subsequently made in the text.

Of the 33 investigators, 28 were institutional and 5 were gynaecologists in private practice. Twenty-nine of the investigators worked in U.S.A. and 4 were located elsewhere. The Lippes loop was studied in sizes A, B, C and D, the Margulies spiral in two sizes (regular and small) and the Birnberg bow in two sizes, 3 and 5.

MATERIAL AND METHODS

The intra-uterine contraceptive devices (IUDs) used in this study were all made of solid moulded polyethylene containing 20% barium sulphate to make them radio-opaque. They are flexible enough to be threaded into a straight tube with a calibre of 4-6 mm. for insertion, and will regain their original shape when placed in the uterine cavity.

Three types were employed - (1) the Margulies spiral, (2) the Lippes loop, and (3) the Birnberg bow.

The Margulies spiral

This is a coiled rod with a solid tail, with seven beads on its distal end which project through the cervix. After fitting, the tail is trimmed so that one bead only is visible at the cervical os. The introducer consists of a Teflon tube 4 mm. in diameter and 25 cm. long. It has an oval marker 5 cm. from its uterine end. The coil is threaded tail first into the uterine end of the introducer, and the oval flange indicates the position in which the device should be inserted to lie in the frontal plane of the uterine cavity. The device is fitted by inserting the introducer through the cervical canal into the uterine cavity as far as the flange; the spiral is then expelled with the stilette. The spiral is made in two sizes - large (marketed as Gynecoil regular) and small (Gynecoil small); only the large size was used in this series.

The Lippes loop

This is in the shape of a double S with tails of coloured

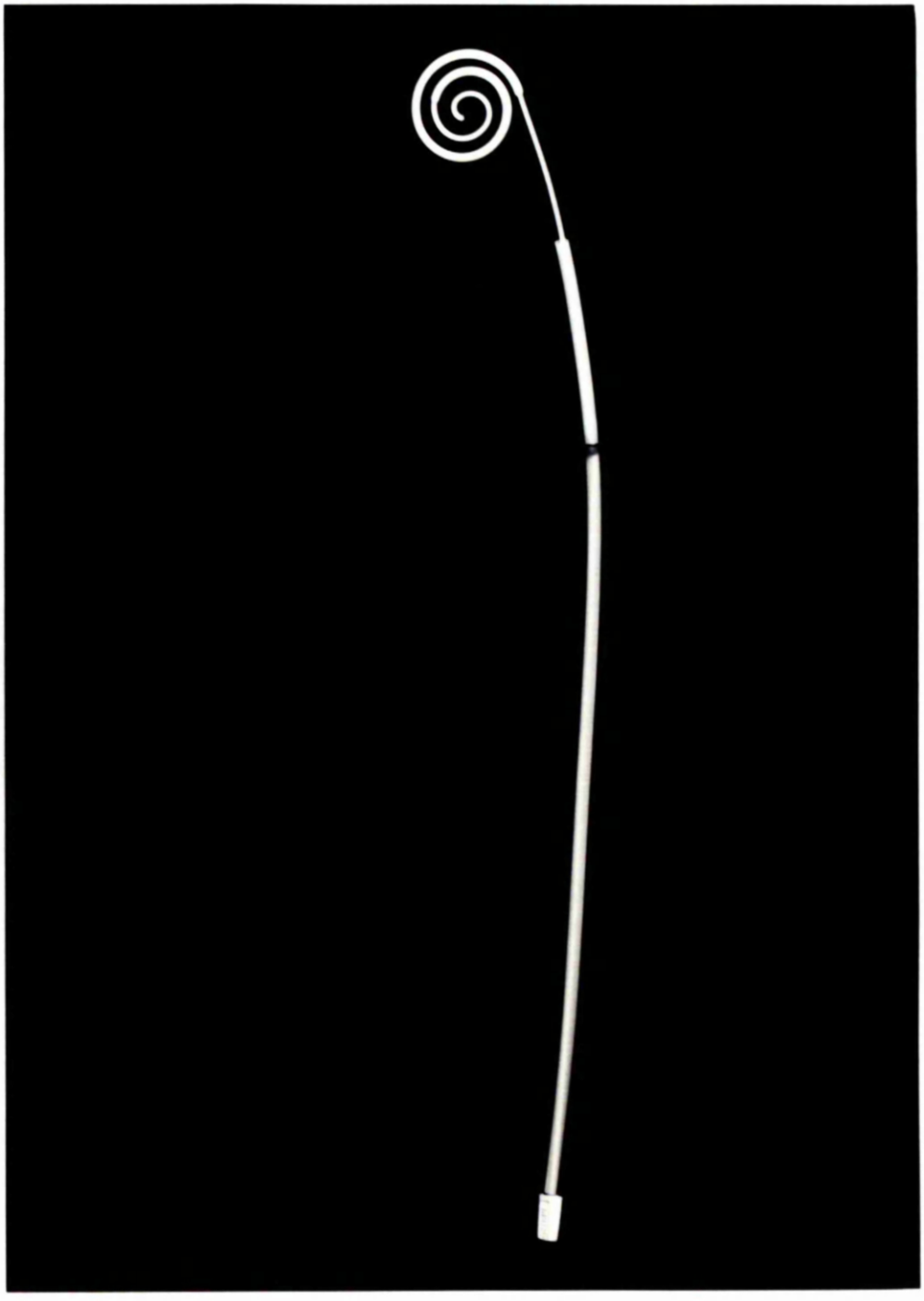

PLATE III

Method of inserting Margulies Spiral into introducer

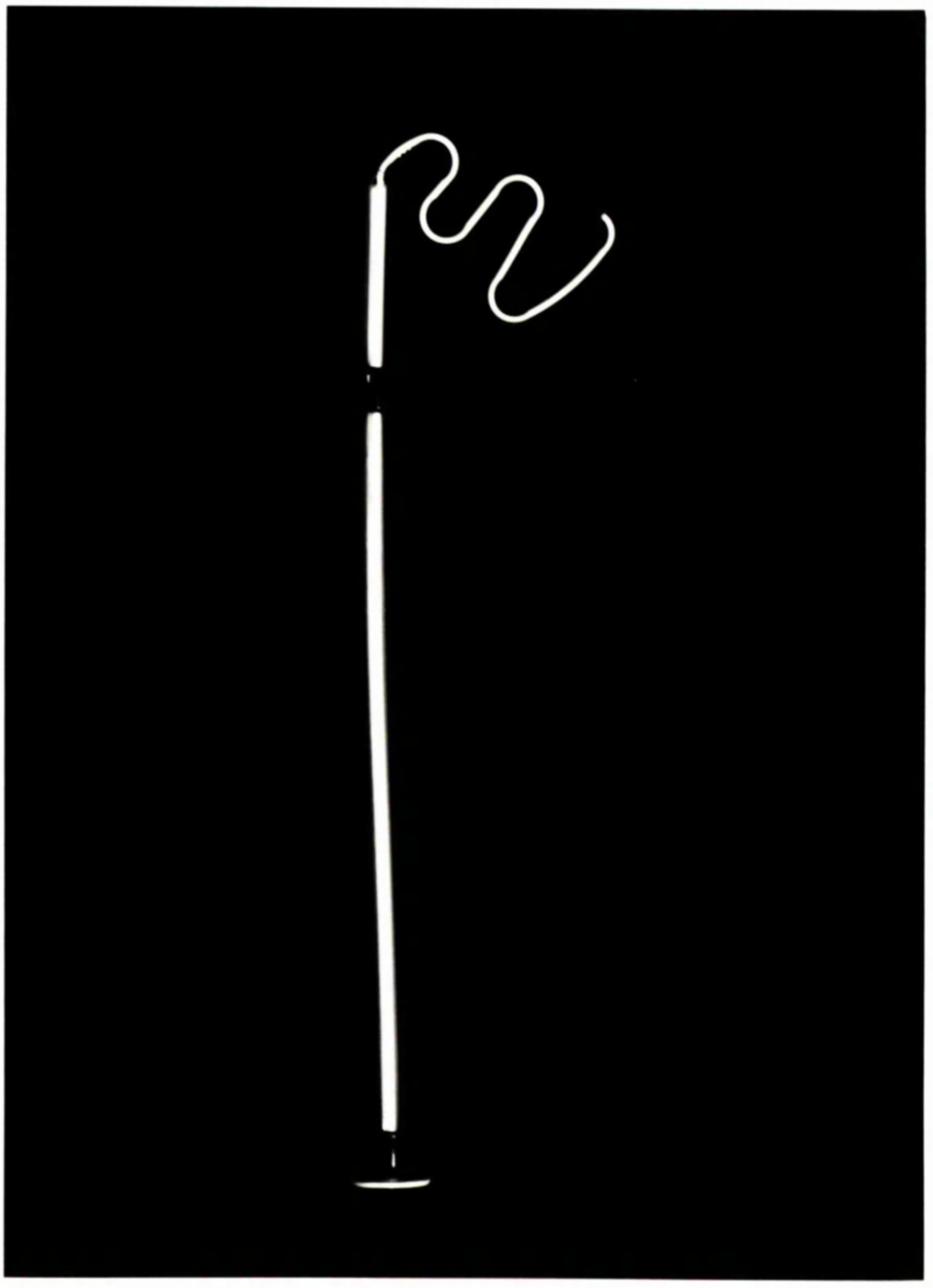

PLATE IV

Method of inserting Lippes Loop into introducer

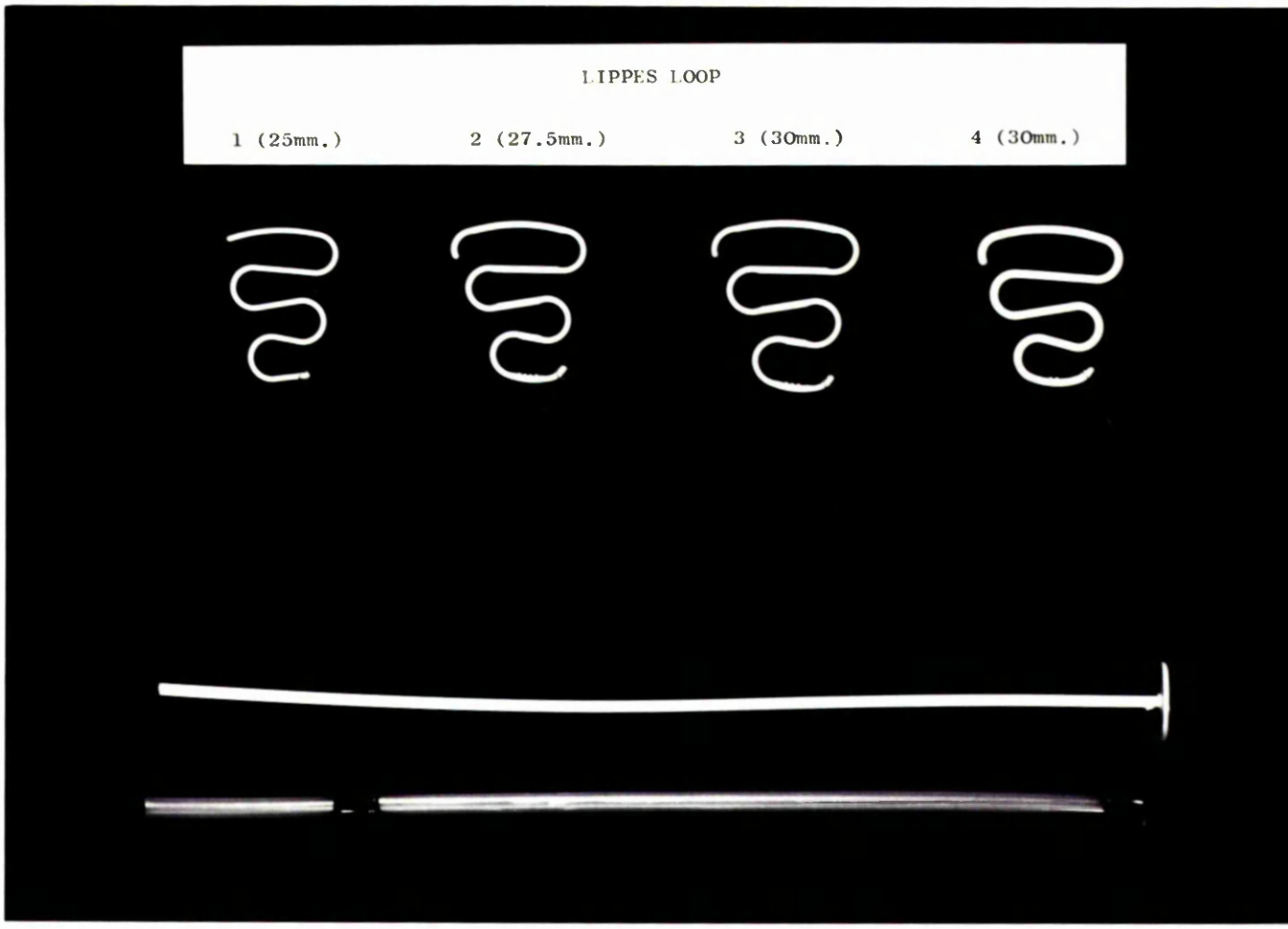

PLATE V

Four sizes of Lippes Loop and introducer

1 A 2 B 3 C 4 D

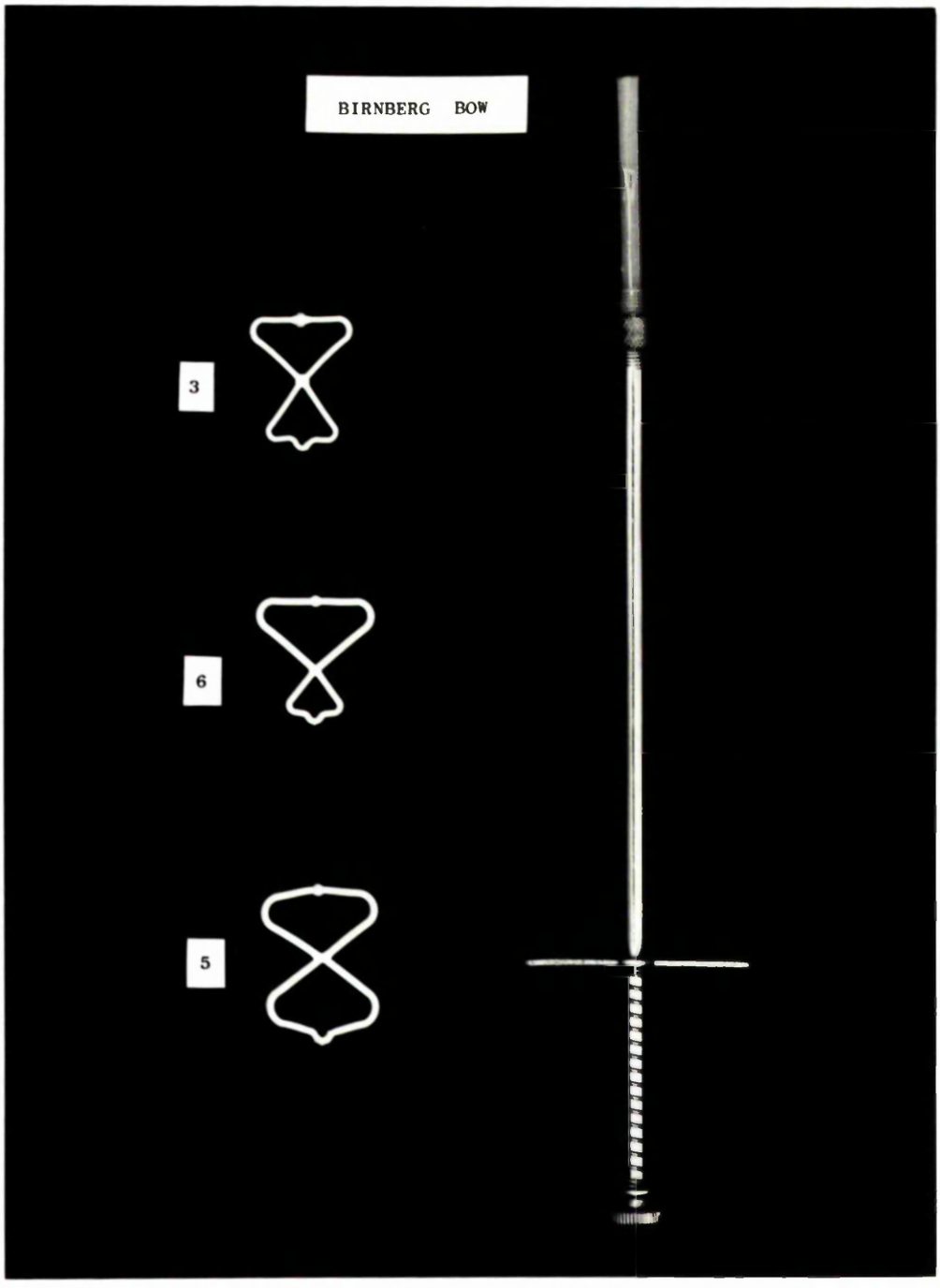

PLATE VI

Birnberg Bows, sizes 3, 5 and 6, with introducer

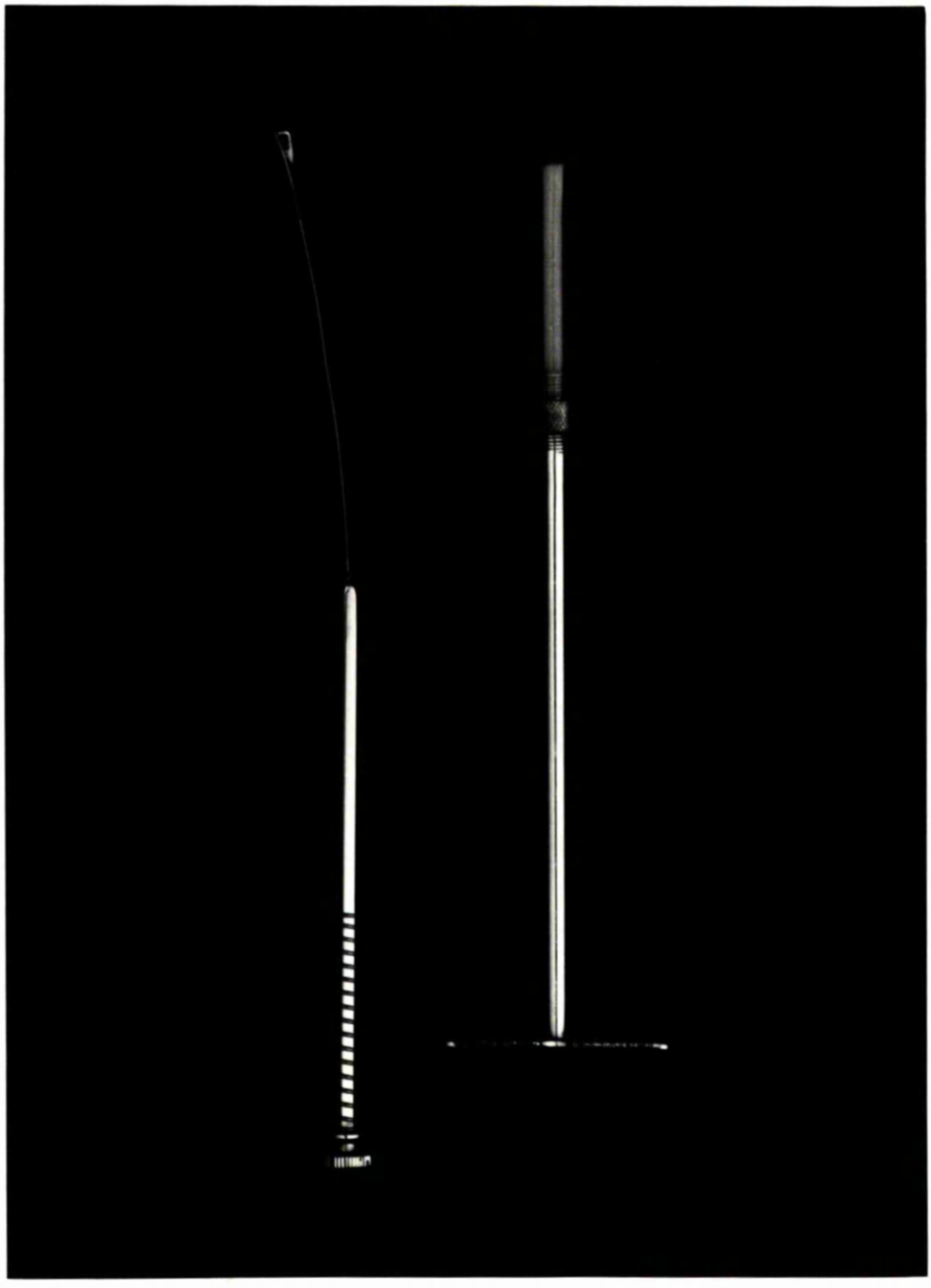

PLATE VII

Birnberg Bow introducer, with plunger removed
to show hook at end for drawing bow
into introducer

PLATE VIII

Birnberg Bow introducer showing details of hook on end of plunger

polyethylene filament (0000) attached to its lower end; the tails project through the cervical canal for easy identification and removal. After insertion the tails are trimmed so that approximately 2 cm. are visible at the external os. The introducer is made of Teflon and has two oval flanges. One of these is 5 cm. from its uterine end and the other at its distal end. These flanges indicate the position in which the device should be inserted into the uterus. The loop is threaded into the distal end of the introducer top end first, the introducer is inserted through the cervical canal into the uterine cavity and the device ejected by pushing it through the introducer with the stilette.

Lippes loops are made in four sizes: loop A (25 mm. across its widest part), loop B (27.5 mm.), loop C (30 mm.) and loop D (30 mm.). Loops A and D were introduced first and are of uniform thickness along their whole length. Loops B and C are reduced in diameter round their curves to make them more flexible. The calibre of the introducer is 4 mm.

The Birnberg bow

This is in the shape of two triangles joined at their apex, and lies completely within the uterine cavity without any cervical appendage. They are made in three sizes - bow 3, bow 5 and bow 6.

The bow is loaded into its introducer by expressing the hook through its uterine end, the bow is placed with its lower end over the hook with the spring pressed back (this will push the device off the hook after insertion) and drawn into the end of the introducer. The

flange on the handle of the introducer indicates the position in which the device should be placed in the uterus. It is expelled by pressing the knob on the handle of the introducer. The calibre of the introducer is 6 mm.

Checking and removal of this device is not easy, as it has no tail. It can sometimes be felt in the uterine cavity with a sound, but being relatively soft at body temperature is not nearly so easy to feel as a Grafenberg ring. The device is removed by a hook or Grafenberg ring remover.

Equipment

1. Bivalve speculum
2. Galley pot for antiseptic solution
3. Sponge holders
4. Allis' tissue forceps (or single-toothed volsellum)
5. Uterine sound
6. Hegar's dilators, sizes 3/4 and 5/6
7. Grafenberg ring remover
8. Long curved scissors
9. Introducer for Lippes loop
10. Introducer for Margulies spiral
11. Introducer for Birnberg bow

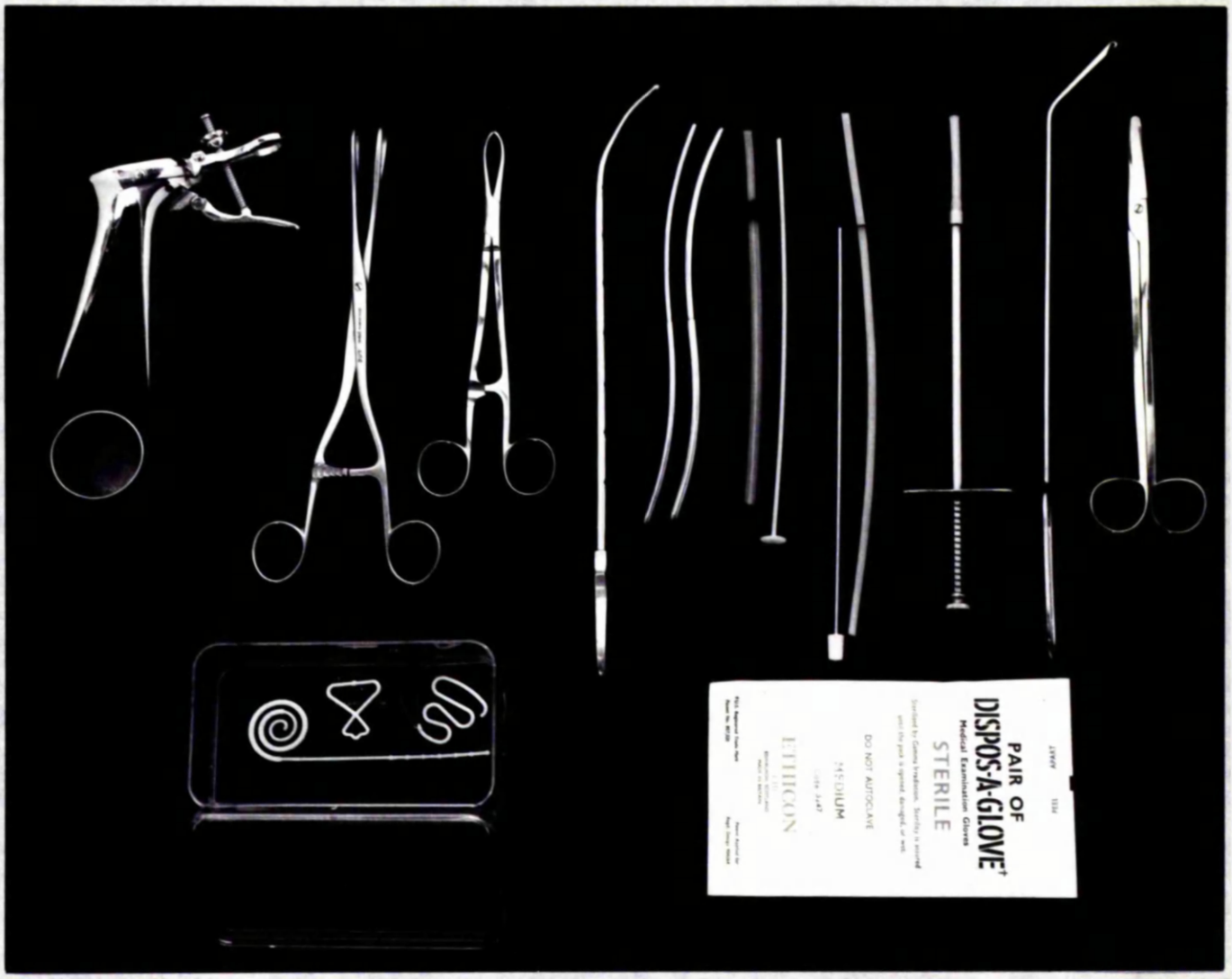

PLATE IX

Instruments required for the

fitting of IUDs

12. Container for IUDs

13. Sterile plastic gloves

A long Spencer Wells forceps was also found useful for threading devices into the introducer with a no-touch technique and for removing tailed devices.

Sterilization

All instruments, including the Teflon introducers, were sterilized by boiling for 5 minutes and placed in a covered sterile container.

The IUDs, which are made from polyethylene, cannot be boiled and were at first sterilized by immersion in a 1:1000 solution of benzalkonium chloride for at least 24 hours before use (in practice they were stored in this solution in a covered jar). In October 1965 IUDs packed in individual plastic envelopes and sterilized by beta-radiation became available. This would seem to be a more satisfactory method of sterilization.

Patients

All patients (with the exception of two very nervous nulliparae and one woman who was already wearing a gold wishbone pessary) were fitted in the clinic, consulting room, or out-patient department of the hospital without anaesthesia or premedication. The patients were not draped and the doctor did not wear a mask or sterile gloves.

Clinic routine

All patients were seen by appointment. The majority had some knowledge of this method of contraception, having read about it, seen it discussed on television or had been told about it by a friend who had already been fitted. Others had been advised to have an IUD by a doctor in a family-planning clinic, hospital or general practice, or by a health visitor or social worker.

In clinic and hospital a consent form was signed by the husband and wife before attendance; joint consent was thought desirable, as this form of contraception is entirely outside the patients' control. In private practice, it was not always administratively possible to obtain the husband's written consent and as a rule only the patient signed the form. The patient's family doctor was informed in every case.

The patient was asked about previous methods of contraception and why she wished to have an IUD. After discussion of the various forms of birth control, it was explained that the IUD did not invariably give complete protection against pregnancy and that the chances of failure were about two to three per cent. It was emphasised that about half these failures were due to unnoticed expulsion of the device and that this was most likely to happen during the first few months after fitting and during the menstrual periods.

Patients were warned that there might be some discomfort and spotting after the device was inserted, that the next period was likely to be much heavier than usual, and that subsequent periods might be

heavier and longer than before.

A routine medical history was taken, with a careful note of the number of pregnancies and their outcome, and whether they were normal or abnormal. Caesarean section was not regarded as a contra-indication, but particular care was taken in the fitting of IUDs in these cases and the more flexible type (Lippes loop C) was usually chosen. IUDs were not fitted if the patient said that she was likely to want another pregnancy in less than a year. A history of heavy or painful periods was given careful consideration but was not necessarily a contraindication to the fitting of an IUD. If there was a history of recent pelvic sepsis or septic abortion an IUD was rarely recommended. Exceptions were occasionally made if it were certain that adequate antibiotic treatment had been given, and no abnormality was found on pelvic examination. This method of contraception was very rarely recommended for nulliparous women.

Ideally IUDs should be fitted towards the end of menstruation or during the following week, but this was not possible as a routine in a busy clinic. However, every care was taken to exclude the possibility of early pregnancy, and no patient was fitted if the period was overdue. Patients were fitted at the earliest eight weeks after a confinement or four weeks after a miscarriage, except for occasional patients of low intelligence who had attended earlier and who might not be expected to return.

Examination and fitting

The patient lay in the dorsal position with her knees flexed and widely separated, and a careful pelvic examination was made to ascertain the size, position and mobility of the uterus and the condition of the adnexa. A sterile bivalve speculum was passed (without lubrication) and smears were taken from the posterior fornix and cervix for cytological examination. The cervix was then swabbed and painted with cetrimide. After grasping the anterior lip of the cervix with an Allis' forceps a sound was passed to ascertain the length of the cervical canal and uterine cavity. The reaction of the patient to the insertion of an instrument into her uterus was noted. Very nervous women were usually found to relax if talked to reassuringly by the nurse or doctor.

The appropriate IUD was inserted into the introducer which was then passed through the cervical canal into the uterine cavity. To avoid contamination great care was taken to ensure that the introducer was passed directly into the cervical canal without touching the vaginal vault or cervix. It is most important for correct placement that the end of the introducer is passed through the internal os. When the os was tight it was sometimes necessary to pass a dilator, Hegar size 4 or 5 (or 6 in the case of a Bimberg bow). If the uterus was ante- or retroflexed slight traction on the cervix helped to straighten the angle at the internal os and made fitting easier. The device was expelled into the uterine cavity slowly. All these manoeuvres were done with the utmost care and gentleness.

After removal of the introducer and tissue forceps the tail of the Margulies spiral was trimmed so that one bead was visible at the external os. At first the threads of the Lippes loop were trimmed so that they were just visible at the cervix, but the threads were often difficult to find at subsequent visits. Later the ends were left at least 2 cm. long after insertion and were trimmed, if necessary, when the device had settled into the uterine cavity. No disadvantages were encountered in this procedure.

Most women were fit to rise from the couch immediately after insertion of the IUD but all were kept under observation for at least fifteen minutes before returning home. They were advised to go straight home and to take things quietly for the rest of the day.

All patients were advised to insert a finger into the vagina after each menstrual period to feel whether the device had been partially or completely expelled from the uterus. Where the IUD had a tail or threads projecting from the cervical os they were taught to feel these. They were also advised to examine any clots passed during the period to make sure that they did not contain the IUD.

No other method of birth control was recommended as a routine but patients already taking oral contraceptives were advised to continue for another cycle in the hope that this would reduce the menstrual flow during the first period after insertion of the IUD.

All patients were asked to return 4-6 weeks after fitting and again at intervals of six months. They were also told to return

immediately if they suspected expulsion of the device or had any abnormal pelvic symptoms. At these return visits, enquiry was made about the acceptability of this method of contraception and about any side effects. A pelvic examination was made and the cervix was inspected. In patients wearing tailed devices there was usually no difficulty in feeling and seeing the cervical appendage; occasionally this was not visible but it could usually be identified in the cervical canal by grasping it with long Spencer Wells forceps. In the rare cases where the tail could not be found and there was no possibility of pregnancy, a straight X-ray was taken of the pelvic cavity. In the early days the uterine cavity was sounded in the patients wearing a Birnberg bow, but when it was reported that expulsion of this device was rare, it was decided that this practice was not really necessary or advisable and it was discontinued.

CLINICAL MATERIAL

A total of 539 patients were fitted with IUDs between February 1964 and December 1966. For all cases the follow-up ended in December 1967. They were grouped into Clinic, Private or Hospital series according to place of attendance.

Clinic series

This consisted of 216 patients attending North Kensington Family Planning Clinic. This is a family planning clinic which has been in existence for 42 years and has its own premises in which 16 contraceptive sessions are held weekly. It is situated in a poor area of London with a large immigrant population, but also draws its patients from much further afield. The majority of women in this series had already had experience of contraceptive techniques and wished to try the IUD as an alternative to other methods which they had found unsatisfactory or unsafe. A few patients were referred by hospitals or local authority clinics for medical or socio-economic reasons. This Clinic series consisted of two groups, A and B. Group A consisted of 179 patients, fitted between February 1964 and May 1965, who took part in a clinical trial of intra-uterine contraceptives sponsored by the Council for the Investigation of Fertility Control. These patients were volunteers who knew that they were taking part in a trial and they paid no fees. A greater variety of devices was used in this group than in any other series. Group B of the Clinic series consisted of 37 ordinary clinic patients fitted between June and September 1965 after the close of the intake to the C.I.F.C. trial. The majority paid the usual clinic fee, which included - besides the initial visit - supervision during the following year.

Private series

This consisted of 170 private patients fitted between May 1964 and December 1966. The majority of these patients had found other contraceptive methods unsatisfactory and had expressed a wish to try the IUD. A few were going abroad to countries where contraceptives were not available. The consulting room is in the 'medical area' of the West End of London, and the fee paid in these cases also included supervision during the first year of use.

Hospital series

This consisted of 153 patients attending the Royal Free Hospital, which is situated in central London adjacent to some poor and overcrowded areas. A clinic for the fitting of IUDs was opened in the Gynaecological Out-Patient Department in September 1965 and all these patients were fitted between then and December 1966. The majority of patients were referred from the Obstetric or other departments of the hospital. A few were referred from local authority family planning clinics for medical or medico-social reasons, because other methods of birth control were considered unsuitable for them. In a few of the hospital cases, sterilization had been advised but refused by the patient or her husband.

Advice on contraception was at this time only available under the National Health Service for those for whom 'pregnancy would be detrimental to health'. The patients in the Hospital series thus differed from those in the Clinic and Private series in that in the two latter the fitting of an IUD was usually requested as a matter of convenience rather than obvious medical need.

The maximum follow-up in each series extends to the end of December 1967, and thus varies in duration for individual patients.

RESULTS OF PERSONAL INVESTIGATION

Age of patients

Most patients were aged between 20 and 39 (Table 1). Fifty-one (9%) were aged 40 or more and only 5 were under the age of 20 (one of these had already had three illegitimate children). The age of the patients in the Clinic and Hospital series was similar, but the private patients tended to be older and 16.5% of the patients were aged 40 years or more. This difference is difficult to explain, but may indicate a greater flexibility of mind in more sophisticated middle-aged women which enables them to try something new in contrast to their less educated sisters who are willing to continue with the same contraceptive methods that they have used for many years. Another possibility - which patients express from time to time - may be that older women prefer to be seen privately, rather than to visit a clinic attended mainly by younger women.

Parity

Table 2 shows the total patients according to parity in each series. The greatest proportion of women - 30%-38% in each series - had had two children. The next largest group (about 16%-23%) had had three children. The private patients were the only series to contain a large proportion of nulliparous women (about 16%). The average family size was larger (3.8) among the hospital patients than among the private or clinic patients (2.2).

It will be seen from the table that only 34 patients had not had children; of these 34, 13 had had abortions. No less than 27 of these 34 nulliparous patients were fitted privately. This is because IUDs are rarely recommended for nulliparous patients at family planning clinics; such patients therefore tend to obtain private advice. Three nulliparous patients were seen at the Royal Free Hospital but these were each referred by a psychiatrist.

Social class

Groupings

In the Report on his Enquiry into Family Limitation, Lewis-Faning (1949) grouped his sample into three social classes instead of the five adopted by the Registrar General. They were as follows:

Class I Professional and non-manual workers

Class II Skilled manual workers

Class III Unskilled workers

It was originally intended to classify the patients in these groups, but since in inner London a larger proportion of occupations are commercial rather than manufacturing, a more practical grouping was found to be:

Class I Professional and managerial workers

Class II Skilled manual and non-manual workers

Class III Unskilled workers

These groupings have been used in the tables which follow.

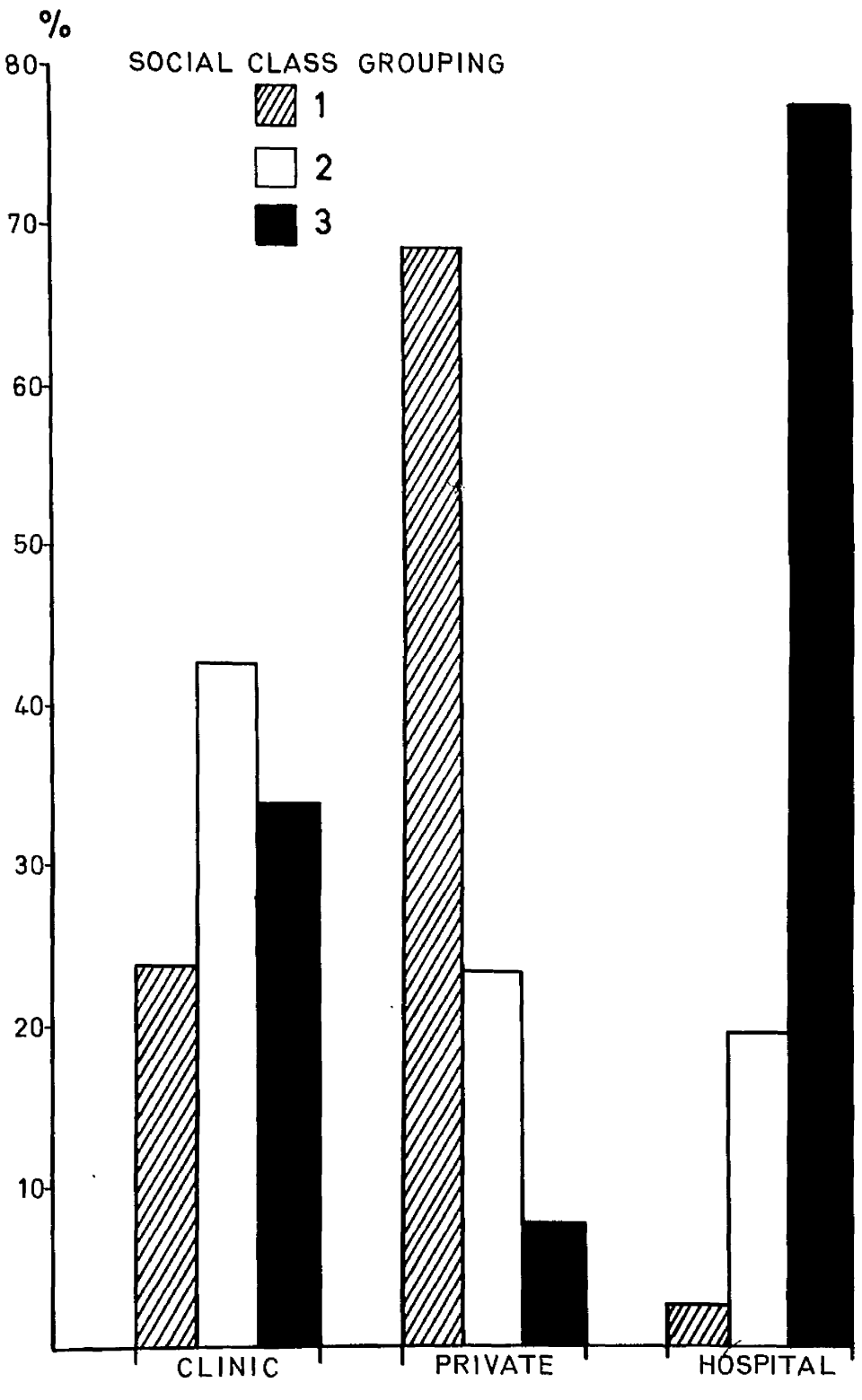
PATIENTS ACCORDING TO SERIES AND SOCIAL CLASS
%
SOCIAL CLASS GROUPING
1
2
3
80
70
60
50
40
30
20
10
CLINIC
PRIVATE
HOSPITAL

Fig.1

Patients according to series and social class

Table 3 and Fig. 1 show the social class grouping in each series. The total patients were fairly evenly distributed throughout each of the social classes but there were pronounced differences in each of the series. As might be expected, there was a much larger proportion of social class I patients in the private series, whereas only 4 of the 153 patients in the hospital series were in this upper social class group; these four patients were all referred for medical reasons.

At the other end of the scale, about 4 out of 5 patients attending the hospital were in social class III. About 8% of the private patients also came within this category. This small group is interesting in that it may be a reflection of our present affluent society in which the unskilled manual worker may earn more than skilled or professional workers of the same age and be more able to afford private consultations.

In contrast to the private and hospital patients, the clinic caters for all social classes with the majority of the patients being drawn from social classes I and II.

Parity and social class

Table 4 and Fig.2 show the parity of the patients according to social class. About one-third of the patients had had two children and about one-fifth had had three. All patients with seven or more children came from social class III. The seven patients in social class I who had five or six children were all from the uppermost and relatively more affluent group of social class I. All seven attended for private

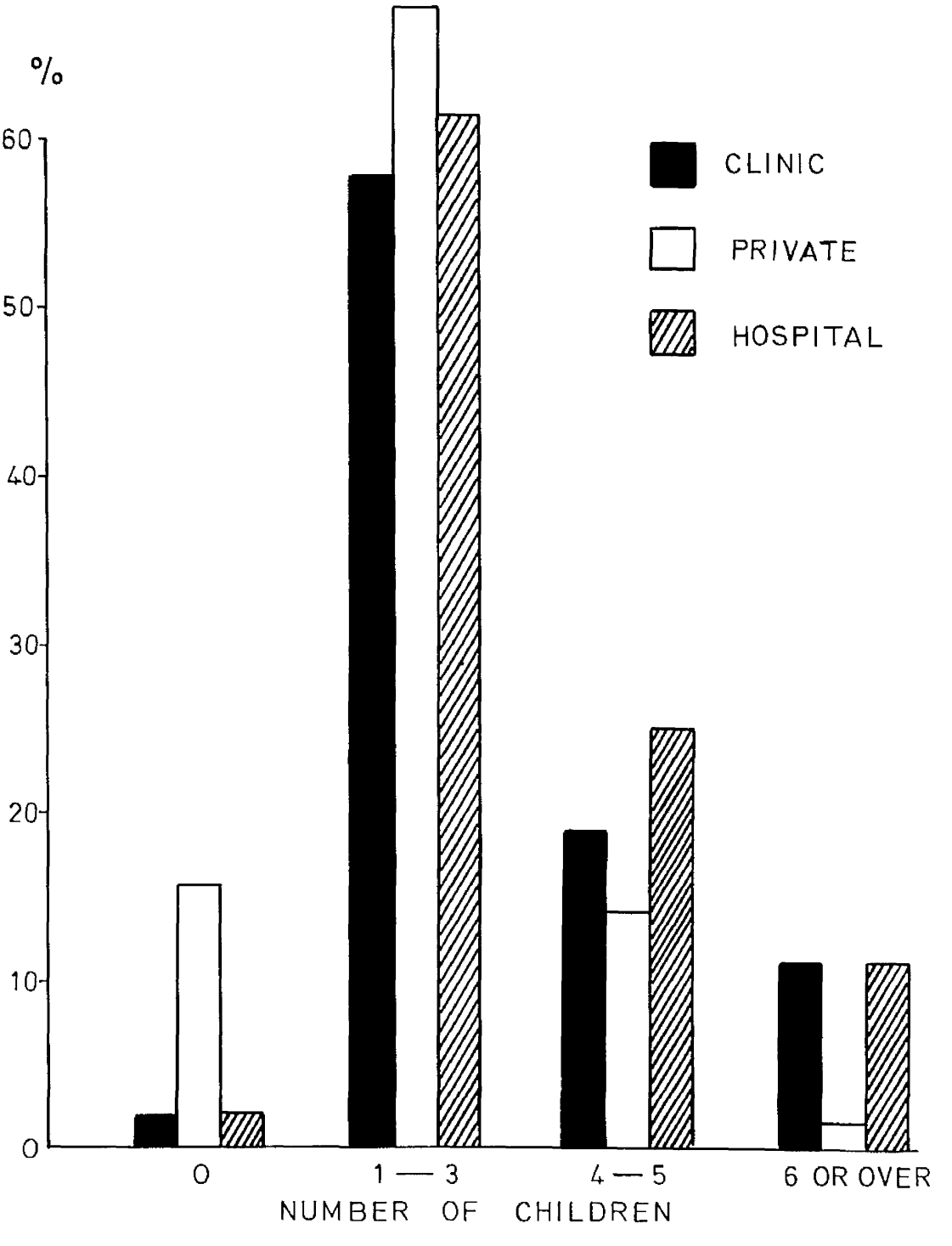
PARITY OF PATIENTS
%
60
50
40
30
20
10
0
CLINIC
PRIVATE
HOSPITAL
0
1 — 3
4 — 5
6 OR OVER
NUMBER OF CHILDREN

Fig.2

consultation.

The average size of families in the three social classes was 2.8. In classes I and II the average size of family was 2.2 (Table 5) (the size that demographers recommend for replacement of the population); in social class III the average family size was 3.8, with a maximum of 4.6 at North Kensington and 3.4 at the Royal Free Hospital. In social class II the average family size among patients who attended privately was less than those who attended the hospital or clinic. It is disquieting to think of the relative increase of social type III patients if the majority of the children in social class III remain in this class and continue to reproduce themselves at the same rate as their parents.

The Census of 1961 showed fertility rates of 21% above average in the lowest social groups, whilst higher social classes have a smaller family than average. A large number of patients attending North Kensington clinic had clearly accepted the idea of family planning and were already using some method, whereas the majority of hospital patients had never used contraceptives. Indeed, many had only thought about family planning for the first time when it was recommended by a member of the staff of the hospital which they were already attending. Many of these patients find it easier to come for this advice to the hospital which they know than to attend a strange family planning clinic. Experience during the survey suggested that to reach those whose need for contraception is greatest, advice should be readily available in maternity units and local authority clinics with which these patients

are already familiar. The problem should be discussed with all expectant mothers and practical advice given as part of the routine of the post-natal visit.

Country of origin

There is a large immigrant population in London, especially in the poor areas surrounding North Kensington and the Royal Free Hospital. Many of these patients belong to the lowest socio-economic groups. This is clearly shown by the finding that only 57.5% of the patients fitted at the Royal Free Hospital were British born. Even at North Kensington and in private practice the number of patients born in other countries was considerable. (Table 6).

The greatest proportion of foreigners fitted were West Indians (8.5%); 7.6% of the patients born outside the U.K. were European - those seen in private practice being mostly German Jewish and those at the Royal Free Hospital Cypriots; 6.1% of patients came from Eire and seemed to find less religious objection to this form of contraception than to other methods - this may be because an IUD is entirely out of their control once the initial fitting is done.

The Census of 1961 shows that immigrant populations have higher birth rates than native-born women. The crude fertility rate (i.e. the proportion of married women who had a baby in the twelve months before the Census) for women from Eire, Cyprus, Malta, Pakistan and India, and West Africa was twice that of women born in England, Wales and Scotland. Women from the Caribbean had a crude fertility rate four

times that of British women.

The use of the IUD, which in the majority of cases was the first and only possible method of contraception for these immigrants, is therefore of considerable social importance.

Reasons for fitting the IUD

The reasons for choice of this method of contraception were as follows:

1. Health
2. Socio-economic - usually associated with too many or too frequent births.
3. Dislike or unsuccessful use of conventional methods of contraception.
4. Anxiety about the use of, or unpleasant side-effects from oral contraceptives. A few patients were referred after taking these for as long as five years. Their practitioners advised these patients not to take an oral contraceptive indefinitely.
5. Other reasons. A small group - which included women with sexual problems in themselves or their husbands - who thought that this type of contraceptive might help to solve these difficulties.

The reason for the choice of the IUD as the most suitable form of contraceptive varied considerably in the three series.

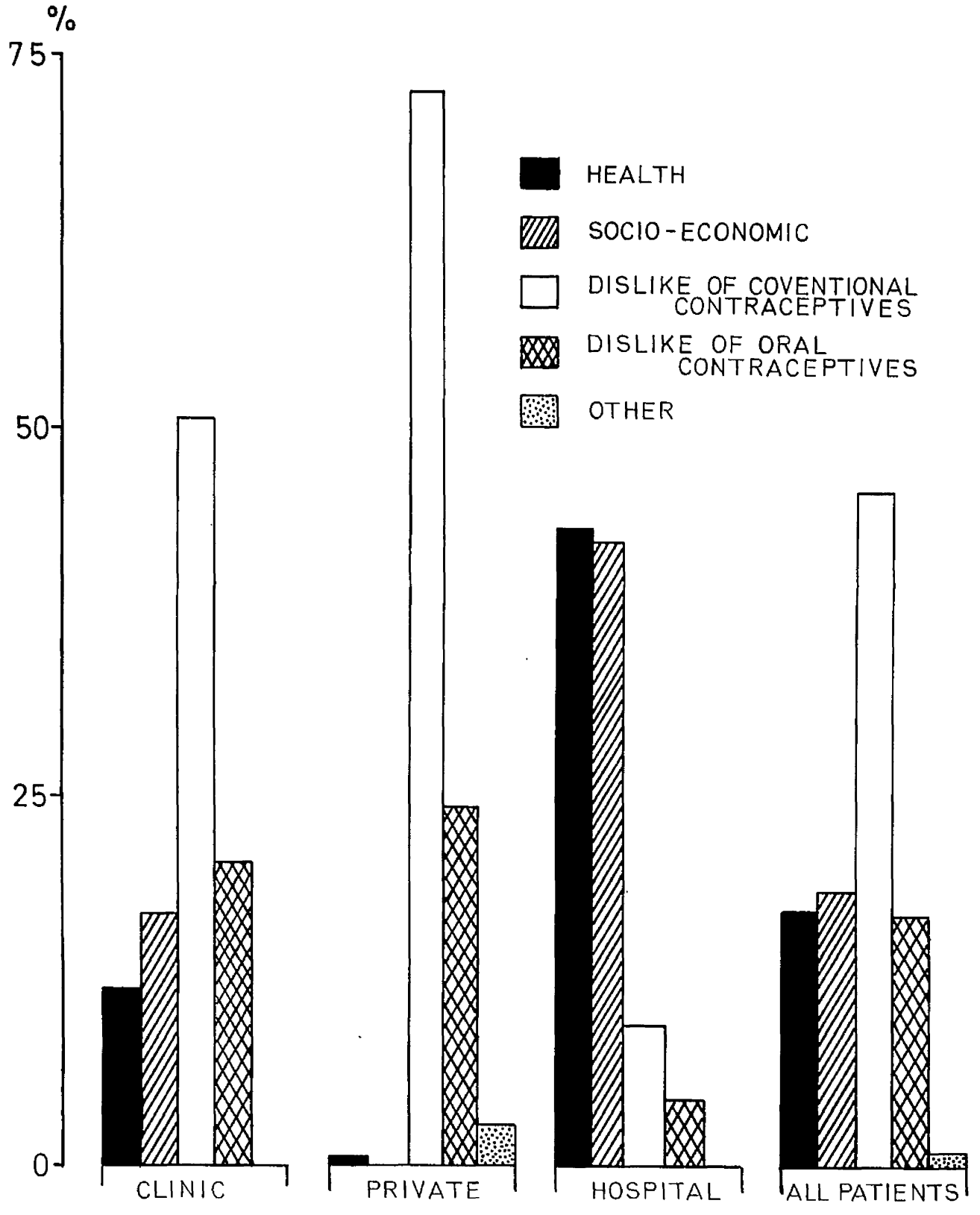
REASONS FOR FITTING DEVICE
%
75
50
25
0
HEALTH
SOCIO-ECONOMIC
DISLIKE OF COVENTIONAL CONTRACEPTIVES
DISLIKE OF ORAL CONTRACEPTIVES
OTHER
CLINIC
PRIVATE
HOSPITAL
ALL PATIENTS

Fig.3

More than 40% of hospital patients were fitted for reasons of health, and in a similar large proportion an IUD was chosen because of a poor socio-economic environment. Relatively few hospital patients had previously used other methods and these patients were fitted because they had disliked or failed with them. In contrast, dislike of other methods - usually conventional contraceptives - was almost invariably the reason why private patients chose an IUD. Dislike of, or failure with other methods was by far the most common motive in clinic patients, but in about a third the IUD was fitted for medical or socio-economic causes. (Table 7). (Fig.3).

The foregoing four conditions were the main reasons for fitting. Only 2.9%, all of whom were in private practice, had the IUD inserted for other reasons, but it is probable that marital problems are more easily discussed in private than in clinic practice, and such problems may also have contributed to the clinic patients' dissatisfaction with other methods.

Table 8 gives a more detailed analysis of the medical and medico-social reasons for the use of the IUD in the Royal Free Hospital clinic. 43% were inserted for purely medical reasons. These included a wide variety of medical conditions but the most common were psychiatric disorders. Oral contraceptives, although highly effective, were contra-indicated in many of these patients because of their medical conditions. Others for whom an oral contraceptive might otherwise have been suitable were incapable of using them effectively.

Sterilization had previously been offered and refused by either the patient or husband in a few cases. On the whole, London women do not seem to accept sterilization so readily as those in Aberdeen (Baird, 1965).

Among those fitted for socio-economic reasons were many immigrants, most of whom were young and had either had a rapid succession of pregnancies and miscarriages, or large families. Most were living in very poor social conditions. Some did not speak English and it would have been extremely difficult to instruct them in other methods of contraception.

Type of device

The great majority of IUDs employed were Lippes loops. In all series a total of 474 Lippes loops, 32 Margulies spirals and 33 Birnberg bows were used. (Table 9). Of the four sizes of Lippes loops, size C was employed most frequently (403). The type and size of the IUD employed was decided by various considerations.

As mentioned previously, at the start of the present investigation, the patients at North Kensington clinic participated in a trial organised by the Council for the Investigation of Fertility Control. Different devices were inserted as received from the Council, without regard for the patients' parity. However, reports published in February 1965, (Tietze, 1965a) and December 1965 (Tietze, 1965b) showed a pregnancy rate of 5.7 and 11.9 with the bow 3 and indicated that it was unsuitable

for use in multiparae. It also became apparent as more experience was gained that devices without a cervical appendage were more difficult to check and remove than those with tails. It was decided that bows were not suitable for routine use in clinics when a patient suffered such severe pain after insertion that immediate removal of the device was necessary. Fortunately a tailed device had been inserted and removal was easy. Had a bow been used great difficulty might have been experienced.

As will be seen from Table 8, devices other than the Lippes loop were only fitted in the early stages of the investigation. The use of other devices for first insertions has now been largely discontinued by the author. Loop C is used routinely by the author for most patients. Nulliparae are usually fitted with loop A (unless they have previously had an abortion, when loop B is sometimes used.) Occasionally multiparae with small uterine cavities are also fitted with loop B. After several pregnancies had occurred in women with large families, wearing loop C, it was decided to use loop D for those with three or more children or whose uteri seemed larger than normal. Whether this size is more effective in these patients is not yet known. The choice of loop D in about 16% of this series indicates the more recent policy of fitting patients of high parity with this size of device. These trends are shown in Table 10.

COMPLICATIONS AT FITTING

Three types of complications occurred during fitting. These were - failure to fit, syncope, and pain. Taking the three series together, all complications were uncommon, slight pain being the most frequent (2.8%). Complications were much more common in private patients than in clinic or hospital patients. (Table 11).

Failure to fit

This occurred once in the North Kensington series and twice in the Royal Free Hospital series, and in each instance was due to a previous amputation of the cervix. In two patients the amputation had been performed during a Manchester repair operation, and in one during a cone biopsy for carcinoma in situ. Insertion of an IUD is always difficult after a Manchester repair, the vaginal fornices may be so narrow that it is almost impossible to expose the cervical stump, which in any case is high up and relatively immobile. In each of the patients mentioned the cervical canal was so stenosed that it was impossible to pass a sound. Contraception may be difficult after a repair operation as it is rarely possible to fit a cap of any type. Six IUDs were successfully fitted after Manchester repairs but the expulsion rate (possibly due to the shortness of the cervix) was 50%, six times greater than normal. Repair operations are most often necessary in women who have had several children, and further delivery may well reduce the benefit resulting from the operation. In consequence future

contraceptive methods should always be discussed with the patient who is to have this operation performed. In some cases tubal ligation at the same time as the operation may prevent much future anxiety. In these cases - many of whom may be in their late thirties or early forties or approaching the menopause - tubal ligation may be a better solution than the prescribing of oral contraceptives. Another possibility is to fit an IUD - possibly a bow - at the time of operation.

Syncope

Cervical shock, as it is sometimes called, may occur as the result of any manipulation of the cervix in a conscious patient, but is most often the result of passing an instrument through the cervical canal. It is said to be due to reflex vagal inhibition and is accompanied by faintness and slowing of the pulse which in some cases may be pronounced. Syncope may occur without any warning or it may follow manipulations which have caused pain, or prolonged attempts to pass a sound or insert an IUD. It is most often seen in highly-strung and nervous patients. Syncope may occur even during a very skilful examination, but it is more likely when the doctor is inexperienced, lacking in confidence and unskilled in the necessary technique.

Cervical shock may range from transient faintness to complete unconsciousness with a slow pulse, low blood pressure and cold sweating. These severe symptoms are sufficiently alarming to indicate that apparatus for resuscitation should always be at hand when IUDs are

fitted. The three cases in this series recovered after lowering the head and elevating the pelvis and legs. The third patient was a very nervous woman who experienced considerable pain after fitting of the IUD, but refused to have it removed: she improved after an injection of 50 mg. of pethedine. The mild cases recovered rapidly after rest. As will be seen from the table, no reactions of this kind occurred in hospital patients.

Mills (1967)[a] reported some degree of shock in 5% of his series of 1,082 patients and suggested that when syncope occurs the possibility of perforation of the uterus should always be borne in mind. However, there was no record of shock in the four cases of known perforation in his series. No case of perforation of the uterus is known to have occurred in this series and the IUD was definitely in the uterus in the three cases mentioned above.

Pain

As will be seen in Table 11, pain occurred most frequently in private patients and most rarely in hospital patients. The three hospital patients who experienced severe pain had each been referred from the psychiatric department. As shown in Table 11, syncope and pain were much more frequent in sophisticated women fitted privately than in either clinic or hospital patients. This may be partly due to personality and temperament, but observer variation has also to be taken into account. In the clinic and hospital groups, the patients were looked after by the nursing staff, whereas in private practice they were

continuously observed by the doctor.

Pain may occur when the uterine sound is passed and if severe may be an indication that the patient will not tolerate an IUD. Pain, similar to dysmenorrhoea, often occurs during insertion of the device and may persist intermittently for several hours. (Frampton & Matthews, (1967), advise that if there is severe pain during insertion the doctor should abandon the attempt before any serious harm is done.) Pain is usually relieved by rest and simple analgesics, but, if severe, pethedine (50 mg. by injection), may be necessary. It is most likely to occur in women who are highly-strung and subject to dysmenorrhoea. Pain is common in nulliparae and is one contra-indication to the use of IUDs in women who have not had children. It is also apt to occur in women who have not had a child for many years. Pain, as well as difficulty in fitting, is also seen in patients who have taken oral contraceptives for some time. Some types seem to make the uterus smaller and harder. (Frith, 1966).

If severe pain occurs immediately after insertion of the IUD it responds quickly to removal of the device. Immediate removal was necessary in six patients in this series, two of whom were subsequently fitted with a smaller device without ill effect. As mentioned above, the occasional need for rapid removal in patients with pain is a strong argument in favour of using tailed devices as a routine. Tailed devices can be removed in a moment, without difficulty, whereas the removal of a Birnberg bow in a patient with uterine spasm and some degree of shock

may be a formidable procedure requiring hospital facilities.

One patient in this series (a highly-strung woman with no children, but a history of one miscarriage) experienced no pain on insertion and was quite well for several hours afterwards. Five hours after insertion she developed colicky pain which did not respond to analgesics and necessitated removal of the device.

Mills (1967a) reported that about half of his patients experienced some pain and that in a few this was quite severe but did not necessitate removal of the device. Satterthwaite & Gamble (1962) reported pain on insertion in 6% of 125 women, in 8% of whom medication was required and 1% removal of the spiral (which was subsequently replaced by a loop which did not cause pain).

Perforation of the uterus

Perforation of the uterus is not known to have occurred in this series.

Mills (1967a) suggested that perforation should be suspected when syncope or severe pain occurs at insertion, but these symptoms were not noted in the four cases in his series, which were all diagnosed later. In the present series there were thirteen cases of severe pain and/or shock (Table 10). In six the IUD was easily removed; of the seven who retained the device, its place in the uterus was confirmed by clinical examination. Tietze (1965c) gives the incidence of perforation as

0.6 per 1,000 insertions for the loop and 5.1 per 1,000 cases for the bow. The bow perforations, which were studied in detail, occurred much more frequently when fitting was done two to six weeks post-partum, especially if menstruation had not been re-established. Mills (1967b) does not accept the alleged danger of fitting in the early puerperium as none of his four cases of perforation was fitted less than three months after delivery. Hall (1967) recorded perforation in 1 of 111 insertions of the bow and 1 in 738 insertions of the loop; all these occurred in patients fitted five to seven weeks post-partum. In Hall's series, perforation occurred most frequently when the operator was inexperienced. Lean (1967) in Singapore reported a very high rate of perforation. In a series of 8,935 insertions of the Lippes loop - the majority up to eight weeks post-partum - there was a perforation rate of 6.8 per 1,000 first insertions. The greatest proportion of these occurred in women fitted four to six weeks after delivery. He did not accept the concept of mechanical perforation of the uterus at the time of fitting. He considered that an area of decreased resistance, usually in the lower uterine segment, was produced by the 'spearhead' of the loop during insertion, the loop subsequently migrating through this weakened area as a result of uterine contractions or involution. Lippes loop D, the largest and stiffest loop, was used almost exclusively in Lean's series. The loops were inserted by qualified doctors although they were not gynaecologists. The majority of his patients were Chinese, who may have smaller uteri than Western women.

Perforation may be suspected if the tails of the loop or spiral are not visible at the external os and cannot be brought down from inside the cervical canal, or if the device cannot be felt within the uterus with a sound. Misplacement of the device may account for some cases of pregnancy. In Hall's 19 cases of perforation, 16 became pregnant, and Mills' (1967b) 4 cases were diagnosed after pregnancy had occurred. Perforation may first be suspected when the IUD is not found with the placenta and membranes after delivery or with the products of conception at abortion. However, Clinch (1965) described one case where a loop was retained in the uterus after delivery and was subsequently removed by curettage.

A straight X-ray of the pelvis will show if the IUD has been expelled, but if it is present will not show its exact location. Its situation can only be accurately determined by hysterography as described by Burnhill & Birnberg (1965) and Mazar et al. (1967). Mills (1967a) suggests that an X-ray taken with a sound in the uterus may also be helpful. In Hall's series of 17 cases, a straight X-ray showed the misplacement in only 4. In contrast, hysterography was successful in revealing the misplacement in each of 8 cases. Lean used radiological examinations including hysterograms, to confirm the diagnosis.

Mills observed no harm to the patient in his 4 cases of perforation and no ill-effects have been described from a misplaced loop. The minimal tissue reactions observed in those cases where laparotomy had been carried out could account for the lack of symptoms

caused by the misplaced loop. The bow, on the other hand, may cause more serious complications. Thambu (1965) described a case of intestinal obstruction due to the incarceration of a loop of small intestine through a bow projecting into the peritoneal cavity. Hall describes two similar cases in his series and advises that all IUDs that have perforated the uterus should be removed by laparotomy or copotomy.

Uterine perforation is usually asymptomatic and will not be suspected unless the possibility of its occurrence is constantly borne in mind and looked for in suspicious cases. Care in examining the patient, judicious timing of insertion and in choice of type and size of device, use of a tenaculum to straighten the uterus in cases of ante- or retroflexion, sounding of the uterus and gentleness during introduction and ejection of the device should reduce the incidence of uterine perforation to the minimum.

FOLLOW-UP

Patients were asked to return one month after the IUD was fitted and thereafter at six-monthly intervals, but were advised to report immediately if they experienced any untoward symptoms or suspected expulsion.

Table 12 shows the total months of use of each type of device in the three series. The total for all devices was 7,481, but by far the greatest number of months of use - a total of 5,533 - is with Lippes loop C. The months of use for the other sizes of Lippes loops and the remaining devices is much less, varying from 54 months of use for loop B to 507 months of use for bow 3.

For Lippes loop C the months of use were greatest in North Kensington (2,583) but were also considerable for private patients and the Royal Free Hospital - 1,673 and 1,277 months of use respectively.

The number of patients examined at the follow-up visits is shown in Table 13 and Fig. 4. This number is greatest in the Clinic series especially at visits more than one year after fitting. This is because there were originally more patients fitted at the clinic than as private patients or at hospital, and also because the clinic patients were fitted earlier. As mentioned above, the clinic patients were fitted between February 1964 and September 1965, whereas the private patients were fitted between May 1964 and December 1966, and the hospital patients even later - between September 1965 and December 1966.

MONTHS FOLLOWED UP – PERCENTAGE IN EACH SERIES

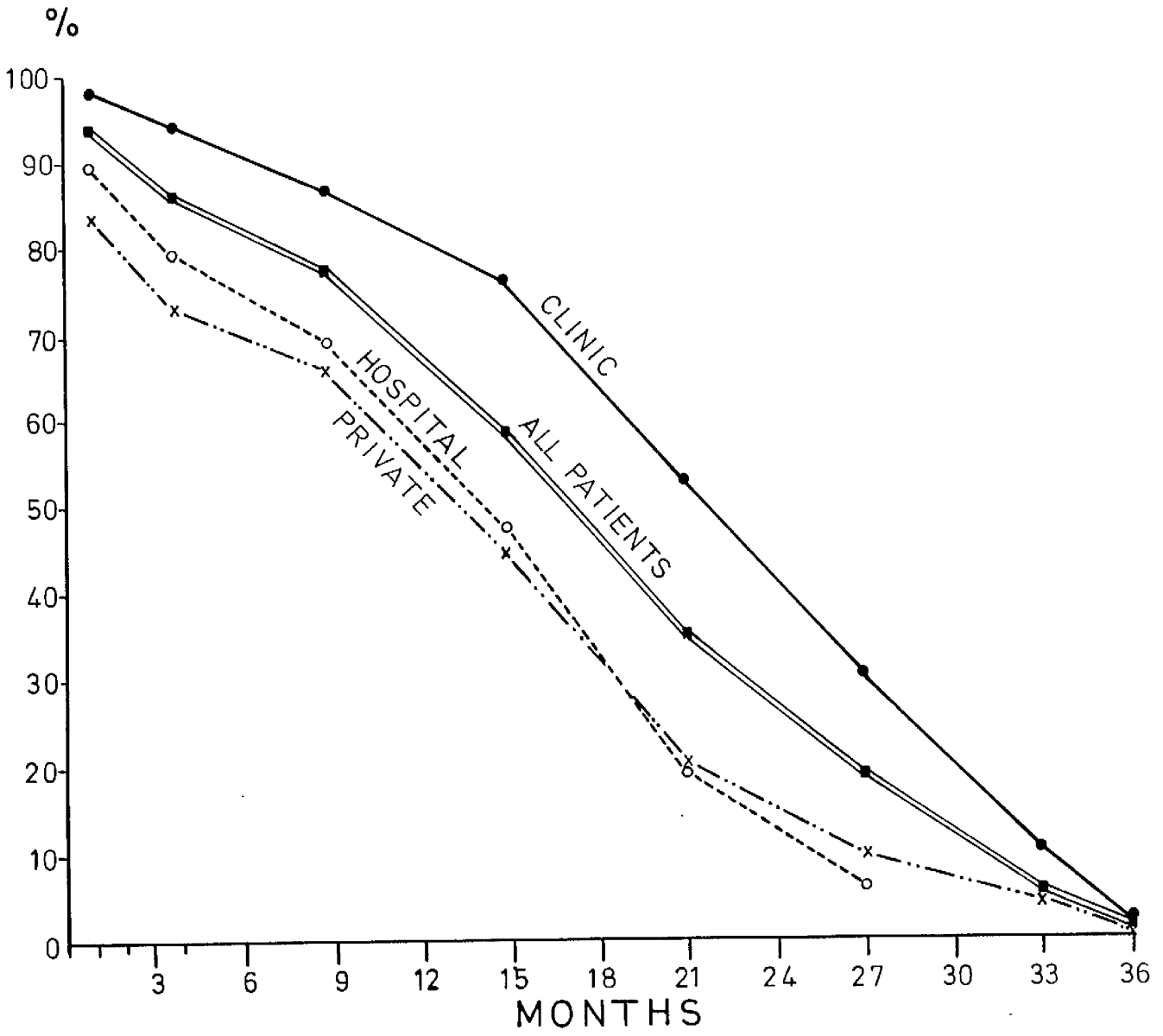

Fig.4

PREGNANCY

Pregnancy rate

Of the 539 patients fitted with intra-uterine devices 29 became pregnant - 23 after a first insertion of the device and 6 following reinsertion after a previous expulsion. The latter - which constitute a special group - are not included in the tables which follow and are discussed later.

The efficacy of contraceptives is usually estimated in terms of 100 woman-years of use. This is calculated by Pearl's formula, $\frac{\text{Failures} \times 1200}{\text{Months of use}}$ and is the method employed in the subsequent analysis.

The pregnancy rate per 100 woman-years of use, according to the device is shown in Table 14. With loop D and the spiral there were no pregnancies. For Lippes loop C the rate was 3.4. This rate was rather greater than loop B which was seldom used but was not nearly so great as the rate with the remaining devices employed; loop A (8.4), bow 3 (7.1) and bow 5 (7.7). Although the months of use with these four devices are not sufficient to enable firm conclusions about their relative efficacy and that of Lippes loop C, the greater pregnancy rate with bow 3 and bow 5 is in keeping with the findings of Tietze (1965). In a large series he also reported similar high rates with these two devices. The two pregnancies which occurred with loop A during 286 woman-months may be a reflection of the fact that loop A was used in nulliparous women only, who are difficult to fit with IUDs.

There were sufficient patients and woman-months of use to make valid comparison of the pregnancy rates with Lippes loop C in each of the three series. The pregnancy rate tended to be rather greater among private patients than among patients in North Kensington and the Royal Free Hospital. The greater pregnancy rate among private patients as compared with those who attended the clinic may be affected by the fact that more of the patients in the clinic series were followed up for a longer period. (Pregnancy is more frequent during the first year after fitting than in subsequent years.) However, the smaller rate at the Royal Free Hospital as compared with private patients was not due to shorter follow-up of the latter; in fact the average duration of follow-up of the Royal Free Hospital patients was 10 months as compared with 13.6 months for the private patients and 16.8 for those at the clinic (see Table 12). The pregnancy rate between the private patients and the Royal Free Hospital patients is in any case small and does not attain statistical significance.

The largest study of the efficacy of IUDs was made by Tietze (1965b) who analysed the results of a follow-up of more than 22,000 women fitted with various types of device. The rate for Lippes loop C, 2.6 during the first year and 1.8 during the second year, was a little less than the rate observed for the identical device in the present series. As mentioned above, the rates for loop A, bow 3 and bow 5 were greater than with the Lippes loop C, in keeping with the findings on the present series.

Pregnancy and length of use

Table 15 shows the number of pregnancies which were diagnosed at each successive follow-up among the patients who returned for examination. It is not possible to know for certain whether other pregnancies occurred among the patients who failed to return. However, the impression gained during the survey, and subsequently, was that many patients who failed to return after a year did not keep their appointments because they found the IUD was satisfactory. It is likely, therefore, that most of the pregnancies occurred in patients who attended for follow-up. Two ectopic pregnancies which occurred in the series were reported from hospital.

Since many patients fail to keep routine appointments after prolonged usage, the proportion of pregnant patients among those who return for examination after one year tends to increase. However, the likelihood of pregnancy is probably less after one year than before. Tietze (1965b), who analysed a series in which almost all patients were followed up found that the pregnancy rate was less after the first year of use than during the initial twelve months.

Pregnancy according to expulsion and period after fitting

The position of the device was confirmed in every case by clinical examination in patients who were wearing a loop and in whom the threads were visible at the cervix or by finding the IUD at miscarriage, vaginal termination, hysterotomy or confinement.

Of the 23 pregnancies, 16 occurred with the device in situ and 5 after expulsion; in the remaining 2 cases the position of the device was not confirmed.

Pregnancy following unnoticed expulsion of the IUD was most common during the first year of use and occurred almost as frequently as pregnancy with the device in situ during this period (Table 16). All the pregnancies in patients followed up after twelve months of use occurred with the device in the uterus. These findings are not surprising. As will be shown later, expulsion is much more common during the first few months after fitting and is much less frequent after twelve months. Two of the pregnancies occurred during the first month of use, but one of these patients was probably pregnant when she was fitted.

Tietze (1965a) reported that in his series 53.6% of patients became pregnant with the device in situ and 46.4% with the device undetermined. His proportions for the loop and the bow are roughly equal.

The proportion of pregnancies with the device in situ in the current series (69%) is considerably greater than in the series by Tietze. However, in the current series, as mentioned above, the position of the device was confirmed in all but two of the pregnancies. X-rays were never advised to show the position of the IUD if the patient was

overdue with her period (but this was done elsewhere in one case in the early days of the trial).

Although Tietze states that the precise time of conception and the precise time of expulsion cannot be known, it seems likely that those patients who reported for examination when the period was a week or so overdue and were found to have the IUD in the vagina expelled it partly or completely from the uterus before they conceived. It seems unlikely that an IUD could be expelled from a pregnant uterus without the accompaniment of some bleeding.

Pregnancy according to parity

With the exception of nulliparae there was a general tendency for the percentage of pregnancies to increase with previous parity, although none of the 43 women with 6 or more children were known to have become pregnant. (Table 17). However, these patients were almost all in poor socio-economic circumstances and attendance at the follow-up visits was infrequent. An increase in the pregnancy rate with parity has been described by Tietze (1967) using loop D only. No nulliparous patients were included in his series.

As mentioned above, the frequency of pregnancy among nulliparae was greater than among women with previous children. A high rate among nulliparae does not appear to have been previously reported. The numbers in the group are small but if confirmed in a larger series would be an additional reason for considering that IUDs are unsuitable for women who have not had children.

Pregnancy according to parity and type of device

Nulliparae are usually fitted with loops A and B and a high rate would be expected from the known high rate of expulsion and pregnancy with the smallest sizes of IUDs, (Tietze, 1965b). Many nulliparae might tolerate a larger loop and receive better protection from it.

In the current series the incidence of pregnancy in women with one child - almost all of whom were fitted with loop C - was low (Table 17), and it would seem that loop C is a suitable device for these women.

The incidence of pregnancy in women with two children (5%) was high. One of these patients was fitted with a bow 3 in the early stages of the clinical trial: it is now apparent that this device is too small for multiparae. Tietze (1965) reported a pregnancy rate of 11.9 with bow 3.

The incidence of pregnancy in women with three children (2.7%) is within the expected range. One of these patients was fitted with a bow 3 and would probably have been better fitted with a larger device.

The incidence of pregnancy in woman with four children (6.6%) is also appreciable. One with bow 3 and three fitted with loop C should probably have been fitted with larger devices. The pregnancy rate with bow 5 is known to be high and bows are not now chosen except for women who repeatedly expel the larger loops.

The incidence of pregnancy in women with five children (7%) is high, and loop D would probably now be chosen for these patients.

In the current series none of the 37 patients fitted with loop D became pregnant, and the pregnancy rate as a whole might have been less if loop D had been used instead of loop C. On the other hand, this was not the experience of Tietze (1965b) who reported a pregnancy rate of 2.6 with loop C as opposed to 2.9 with loop D. However, in Tietze's series the removal rate for medical reasons was greater with loop D than for loop C. Lean (1967) using loop D had a much greater incidence of perforation of the uterus than has been reported elsewhere and although this may be partly due to the fact that the majority of women in his series were fitted up to eight weeks post-partum, the relative rigidity of loop D as opposed to loop C may make perforation of the uterus more likely.

These findings suggest that the IUD may not be sufficiently reliable for women of high parity, but many such women are highly fertile and of low intelligence, and likely to fail with any form of contraception. Tubal ligation is probably the only effective method in many cases; if ligation is not possible and an IUD is to be used, Lippes loop D should be chosen for high parity patients.

The individual pregnancies

Table 18 gives details of each pregnancy which occurred in this series. The following cases are of special interest.

Case 1 is the only one in which the IUD was probably inserted in very early pregnancy. The patient's last period had occurred on 16.8.66 and she was fitted on 9.9.66. She had bleeding when her next period was due and intermittently until she aborted, expelling the IUD on 14.10.66. The abortion was complete, and when the sac was opened it was found to contain a foetus 1 cm. in length, the maturity of which was estimated at 8 weeks.

Case 3 was the first patient who was fitted with an IUD. She did not return to the clinic. She went to hospital after 18 weeks of amenorrhoea, where an X-ray showed the foetus and IUD in situ. She had a normal delivery at term and the bow was expelled with the placenta. Puerperal sterilization was carried out. X-rays are not usually recommended during early pregnancy and it is difficult to know why this one was advised.

Case 7 became pregnant with the loop in situ after 5 months. She missed one period and then began to spot: a pregnancy test was positive. Spotting continued and the uterus did not increase in size and a diagnosis of missed abortion was made. This was confirmed at curettage and removal of the device 8 weeks after the last period. She conceived again subsequently and had a normal pregnancy.

Case 22, a para 4, had been fitted with a bow 5 and conceived after 20 months with the device in the uterus. After some bleeding in late pregnancy - associated with a breech presentation - she was found to have a central placenta praevia. Caesarean section with tubal ligation was performed at term, and the bow was found in the placenta. The baby was healthy.

Case 23 was referred by a psychiatrist. She had had no children but had already had one pregnancy terminated. She was fitted with a loop B, but unfortunately conceived after 20 months with this in situ. The pregnancy was terminated at 8 weeks on psychiatric advice. She is only 23 and it will be difficult to advise her as to her future method of contraception.

Pregnancy after re-insertion

Thirty-four patients were refitted with an IUD after one previous expulsion and the pregnancies which occurred in this group have not been included in the previous tables. Of these 6 became pregnant, 3 with the device in situ and 2 after expulsion: one expulsion was noticed and one was unnoticed. The position of the device in the sixth case is not known. (Table 18, Section B).

No pregnancies are known to have occurred in the 7 patients who were refitted after two previous expulsions.

Case 4 was a West Indian woman, para 5, with hypertension, fitted with a loop D. She knew that she had expelled her device but did not

report until her period was overdue. Hysterotomy and sterilization was performed and she was found to be carrying twins.

Case 13 had an ectopic pregnancy after wearing loop C for 9 months, the loop was removed at the time of salpingectomy and she was subsequently fitted with another loop C. She was well when seen again 6 months later.

Case 15, a para 2, was refitted with a loop B after expelling a loop C as she was thought to have a small uterine cavity. She conceived 12 months later and has been lost to follow-up. It is not known whether the loop was in place or not.

Case 18, a para 4, was refitted with a loop D after expelling a loop C. She conceived 15 months later following unnoticed expulsion, probably during a heavy period. Vaginal termination was carried out as she already had one child suffering from an hereditary muscular dystrophy: she refused sterilization and is now taking oral contraceptives.

Case 25 had had 4 children and 3 self-induced abortions and was fitted with a bow 5 after expelling a loop. She had an ectopic pregnancy 22 months later and the IUD was left in situ when salpingectomy was performed.

Case 28, a West Indian with 6 children, was refitted with a loop D after expelling a loop C. She conceived 25 months later with the IUD in the uterus: she did not seem unduly concerned about this and the pregnancy is continuing.

Outcome of pregnancies

Table 19 summarizes the outcome of all pregnancies occurring in this series: 23 were after first insertion of the IUD and 6 after second insertion following an expulsion. In 19 the IUD was in situ, in 7 it had been expelled and in 3 its position was not known.

All but three of the patients who were known to have become pregnant with the IUD in situ have been followed up; in the three full-term deliveries the IUD was expelled with the placenta. All the children were normal. The most interesting case is that of central placenta praevia associated with a bow; it is thought that the contraceptive action of IUDs is due to their causing some upset in the mechanism of implantation of the fertilized ovum, and it is possible that in this way the bow may have been partly instrumental in causing the ovum to settle in the lower segment of the uterus. One other case of placenta praevia has been reported by Satterthwaite et al. (1965) - this was marginal with the loop lying free on the maternal surface of the placenta.

The incidence of abortion in pregnancies with the IUD in situ (21%) is lower than Tietze's (36.4%) (1965a). In the two patients who were known to have had a spontaneous miscarriage, there was spotting from the time of the first missed period, suggestive of unsatisfactory implantation of the ovum. One of these patients was fitted in the premenstrual phase when she was probably already pregnant. Tietze (1965a)

states that in the few cases when an IUD was inserted into a pregnant uterus, half of the patients aborted. The other two patients who miscarried in the current series were known to have been upset about the pregnancy and although they denied interference this cannot be excluded. One had a septic abortion.

Termination of pregnancy was performed eight times - four times by the vaginal route. In two of these instances the patient sought termination privately: in one other case it was advised for eugenic reasons, the patient refusing sterilization, and in the fourth case for psychiatric reasons - the psychiatrist did not advise sterilization. Hysterotomy and sterilization was performed in the remaining four patients, each of whom had had several children and had good medical reasons for sterilization.

Tietze (1965a) records only five therapeutic abortions in his 247 pregnancies, whereas Mills (1967) in his series had 44 pregnancies of which 23 were terminated. Mills describes the frequency of artificial termination (52.2%) as being due to the underlying medical reasons for fitting of the device or the intensity of the emotional reaction to pregnancy in his patients. All the terminations in the current series were performed before the debates leading to the Medical Termination of Pregnancy Bill of 1967, which has brought about a more permissive attitude towards the subject of abortion. Even so, the majority of the other women in this series did not seek an abortion and seemed to be quite happy to continue with their pregnancies. Two Roman Catholic

women - one of whom had 4 and one 5 children - were offered puerperal sterilization, but only one accepted. The main anxiety of most patients who become pregnant with an IUD in the uterus was that it might have some ill effect upon the baby. An attempt was made to reassure them about this. Tietze (1965a) showed that there was no significant difference with regard to stillbirths and neonatal deaths between those who conceived with the device in situ and those with the position of the device undetermined, nor did the rate in either group differ significantly from the national average. No congenital abnormality was found in the surviving infants in his series.

Of the 29 pregnancies in the series, 2 were ectopic (6.9%). A high ratio of ectopic to uterine pregnancies is a feature of IUDs. Tietze (1965a) reported that about 5% of pregnancies occurring in women wearing IUDs were ectopic, whereas only about 1% of pregnancies in women not wearing IUDs were ectopic. Chun & Dodds (1966) reported that about 2% of pregnancies in Hong Kong women wearing IUDs were ectopic.

It should be clearly understood that it is only the ratio of tubal to intra-uterine pregnancies which is affected by an IUD. The total frequency of tubal pregnancy in women wearing these devices is clearly very much less than in women not wearing them. Thus the IUD is more effective in preventing intra-uterine than tubal pregnancy but does not increase the likelihood of the latter, despite the widely held view to the contrary. The fact that the two ectopic

pregnancies in this series occurred after reinsertion of an IUD is interesting but probably not significant.

Satterthwaite et al. (1965) advised removal of tailed devices in early pregnancy if this is possible and did not find that removal provoked abortion. In six pregnancies where the spiral could not be removed, there were three abortions and one case of abruptio placentae, whereas the two patients from whom it was removed early in pregnancy went to term uneventfully. These authors had similar experiences with the loop. However, removal of the device during early pregnancy has not been recommended by other authors.

The IUD was not removed during early pregnancy in any of the cases in this series. Removal would not appear to be advisable except before 6-7 weeks when the ovum has not yet filled the uterine cavity and when the device is obviously lying low in the uterus or in the cervical canal with the pregnancy above it. Removal of the device should only be carried out in hospital where immediate treatment would be available if haemorrhage were provoked. Even under these circumstances the ethics of the procedure might be open to question.

Management of the patient when pregnancy is diagnosed

The occurrence of pregnancy is naturally a disappointing experience to most women who have relied upon an IUD for contraception,

and may place a strain on their relationship with the doctor. The IUD is the only contraceptive method (apart from sterilization) for which the patient has very little responsibility. She is only required to watch for expulsion of the device and report immediately if this is suspected.

The transfer of the major responsibility from the patient to the doctor has advantages when dealing with patients of low intelligence and motivation for family planning, but has drawbacks where more sophisticated women are concerned. In fact, some women will not want to have an IUD when they are told that it does not give complete protection against pregnancy. Intelligent women can be relied upon to use a mechanical method of contraception consistently or to take oral contraceptives regularly. If one of these patients becomes pregnant while using a cap or an oral contraceptive (which is unlikely) there is always the chance that pregnancy was due to error on her own part, but if she becomes pregnant while wearing an IUD she is more likely to blame the doctor.

Before the device is fitted it is therefore important to impress on all patients that an IUD does not give complete contraceptive protection. The lack of complete protection may not assume so much importance when dealing with women of low intelligence for whom other methods of contraception will be inadequate, but the lack of absolute certainty must be stressed with intelligent women, who must make the choice for themselves after hearing of the advantages and disadvantages

of the IUD as compared with other methods. But however clearly these issues are put at the outset, many women who become pregnant while using an IUD feel very resentful, and a doctor fitting IUDs must be ready to deal with this situation. It is important that the patient should have the opportunity for a private and unhurried interview and that the doctor should not become emotionally involved despite unjustified criticism. As the interview continues, it will often become clear what practical steps should be taken. Some patients, after expressing their initial resentment and disappointment, will be quite happy to continue with the pregnancy when they are reassured that the IUD cannot harm the baby in any way. Appropriate arrangements should be made for their antenatal care and confinement. In grande multiparae the question of puerperal sterilization should be discussed and arranged. In others the question of termination of the pregnancy - with or without tubal ligation - will arise. If there is any medical or psychiatric condition which has to be considered, they should be referred without delay to an appropriate specialist for an opinion as to the advisability of termination. Those who wish to have the pregnancy terminated for social reasons may find this easier since the Medical Termination of Pregnancy Act of 1967. How far the failure of this method of contraception can be regarded as an indication for therapeutic abortion will have to be considered in each individual case.

EXPULSION

Expulsion rate

Of the 539 IUDs fitted for the first time, 49 were expelled, giving an overall expulsion rate of 7.9 per 100 woman-years of use. As will be seen from Table 20, the expulsion rate of loop A, which was only used for nulliparous patients, was the greatest (21.1 per 100 woman-years), followed by that of the spiral (17.9 per 100 woman-years). Loops C and D had an expulsion rate of 7.6 and 2.5 respectively, and loop B 2.3. In the series there was no expulsion of the bow (except after one re-insertion). The expulsion rate for loop C was very similar to that reported by Tietze (1965b) who also reported high expulsion rates with loops A and B and the spiral. The expulsion rate for the larger loops reported by Mills (1967a) was also similar to the present series.

Expulsion related to length of use

The number of expulsions in each six-monthly period after insertion is shown on Table 21.

It is evident that expulsions are very infrequent after 18 months have elapsed since the fitting of the device. Most series (see Tietze, 1965b above, and Mills, 1967a) observed a pronounced reduction of the expulsion rate with time. Mills (1967a) found that 70% of his expulsions occurred during the first three months.

In the present series the expulsion rate showed little tendency to decline until 18 months after the insertion. However, the patients observed to have expelled the device in the present series were probably highly selected inasmuch as known expulsion would be expected to encourage a patient to return for examination.

Diagnosis of expulsion

Expulsion of an IUD may be complete into or from the vagina, or partial, requiring removal from the cervix. The patient may see that the IUD has been expelled, or feel it in the vagina or projecting from her cervix when she makes a routine examination as advised after her period. She may suspect that a tailed device has been expelled if she cannot feel the vaginal appendage, when she could previously feel this quite easily. Occasionally the male partner will feel the IUD projecting from the cervix or lying in the vagina.

An IUD is unlikely to be effective in preventing conception unless it is placed in the upper pole of the uterine cavity. Approximately 50% of pregnancies during the first year after insertion are due to displacement of the device, and it is most important that displacement should be recognised as soon as possible after it occurs. The patients in the series were advised to check the device regularly and to report immediately if displacement were suspected. As stated above they were also advised to report one month after fitting and at

six-monthly intervals thereafter. Of the twenty-three pregnancies after first insertion in this series, five occurred after expulsion of the device, but in only one case was this noticed by the patient. Regular examination may also bring to light some expulsions which would otherwise not be noticed. In three cases in which the patient reported because she was overdue with her period, the loop was found to be lying in the vagina.

It is not always possible to tell in the pregnant patient whether the IUD is in the uterus or not, even when the device has a trans-cervical appendage. If the IUD is situated high in the uterine cavity, its tail may be drawn up as the uterus enlarges, even in the early weeks. If the IUD is situated in the lower segment the threads may continue to project from the external os throughout pregnancy. Unless the vaginal appendage of the device is visible, the pregnancy must be regarded as having occurred 'with device undetermined' until its presence or absence is confirmed at delivery or abortion. X-rays which would confirm the presence of the device are inadvisable during pregnancy.

Apart from those who became pregnant, about 50% of patients noticed that the device had been expelled and brought it back to the clinic with them. A smaller proportion suspected displacement and returned for re-examination. In others the IUD was found in the vagina or projecting from the cervix at routine follow-up, particularly during the early months of use. Diagnosis was easy in these cases, but was much more difficult if upon routine examination the tail of the IUD

was not visible at the external os and could not with a long Spencer Wells forceps be brought to the exterior. In some cases the device could be felt within the uterus with a sound, but the plastic IUDs used in this series were not nearly so easy to feel as rings made of metal.

The solid tail of the Margulies' spiral must be cut flush with the cervix or it may cause damage to the posterior vaginal wall or discomfort to the male. When Lippes loops were first used, it was advised that their threads should also be cut very short. This may have been because of the fear that they might cause irritation to the epithelium of the squamo-columnar junction of the cervical os, or encourage the transmission of infection from the vagina to the uterine cavity. The shortness of the threads made subsequent recognition difficult in many cases, particularly in the premenstrual phase when the uterus is engorged and the threads drawn up into the cervical canal. Recently the threads of the loop have been left 2 cm. or more long without any apparent ill-effect and checking of the position of the device, both by doctor and patient, has become very much easier.

As the types of IUD used in this series were all radio-opaque, a straight X-ray of the pelvic cavity showed when a device had been expelled, but, if it were seen on the film, not whether it was in the uterus or outside. All X-rays in the series were taken during or just after menstruation when the possibility of a very early pregnancy could be excluded. The presence of the IUD in the uterine cavity can only be

shown for certain by hysterography. Straight X-rays were done as a routine in cases of suspected expulsion in this series. These confirmed the diagnoses in the majority, but hysterography was done in six cases. In one the examination demonstrated the presence of the loop upside-down in the uterine cavity, having drawn its threads up with it. This patient had been fitted six weeks postpartum, probably before full involution of the uterus, which may account for the change in position of the device. Hysterography was done in this instance to exclude perforation of the uterus as perforation is most likely to occur in patients fitted soon after delivery.

Mazar et al. (1967) performed hysterographies on fourteen patients in whom the threads of the loop had disappeared and found the IUD in place in ten. The device had turned upside-down in one uterus with a long conical cavity and was lying across one arcuate uterus. In one patient the IUD was found to have perforated the uterine wall. In two of their 100 patients they found two IUDs in the uterine cavity; evidently a second device had been inserted without confirming that the first had been expelled.

Causes of expulsion

There is usually no obvious reason for expulsion but the rate is increased when the operator is inexperienced. For example, in July 1966 one patient was fitted by the author with a loop C, having expelled similar loops twice when fitted elsewhere. In December 1967

this patient reported that no further expulsion had occurred. An inexperienced operator may tend to fail to place the IUD in the uterine cavity with its uppermost part in contact with the uterus. If part of the device lies within the cervical canal it seems likely to stimulate uterine contractions and expulsion of the IUD. Pike (1967) reported a high rate of expulsions in women fitted in Uganda, whether this was due to some idiosyncrasy in African women or to other causes, is not yet known. 19.6% of the 51 negresses in the current series expelled their IUDs. This proportion is more than double that of the series as a whole.

Some cases of expulsion appear to be due to a patulous internal cervical os through which a Hegar dilator size 7 will pass without any resistance. Others, associated with a short and wide cervical canal following a Manchester repair operation, may also be due to a patulous os. Of the 6 patients fitted after previous repair operation, 3 expelled the loop. Abnormalities in the shape of the uterine cavity, such as an arcuate or sub-septate uterus may be a cause of expulsion (and also of pregnancy with the IUD in situ). However, X-rays have shown that the IUD can orientate itself to some extent to fit into the uterine cavity (Birnberg & Burnhill, 1965, and Mazar et al. 1967).

When possible a hysterogram was done in cases of repeated expulsion to see whether there was any evidence of abnormality in the shape of the uterine cavity or abnormal width of the internal os.

Technique of hysterography

The patient lies in the dorsal position on the X-ray couch, a bivalve speculum is inserted and the cervix exposed and grasped with tenaculum forceps and the injection nozzle inserted into the cervical canal. In Burnhill & Birnberg's method (1965) 0.5 to 0.75 ml. of Ethiodol is then injected and the first film taken. This shows the device clearly with some of the surrounding uterine cavity. 4 ml. of the contrast medium are then added and a second film taken. This usually shows the entire cavity but obscures the IUD. Careful superimposition of the two films enables the exact relationship of the device to the surrounding uterine walls to be defined. In the present series this technique was used, but 45% Urografin was employed as the contrast medium. Mazar et al. (1967) first take a straight X-ray of the pelvic cavity and then inject 5-9 ml. of 25% Urografin. The density of the contrast medium in this method is not great enough to obscure the IUD. Where an image intensifier with a television screen is available the examination can be done under direct vision, with a very small exposure to radiation, and even more information can be gained.

Hysterography was carried out in six patients in the series including four patients who had expelled the IUD twice; no gross abnormality in the shape of the uterus was demonstrated but three patients were found to have a long narrow uterine cavity, the width of the fundus appearing to be narrower than that of the loop (30 mm.)

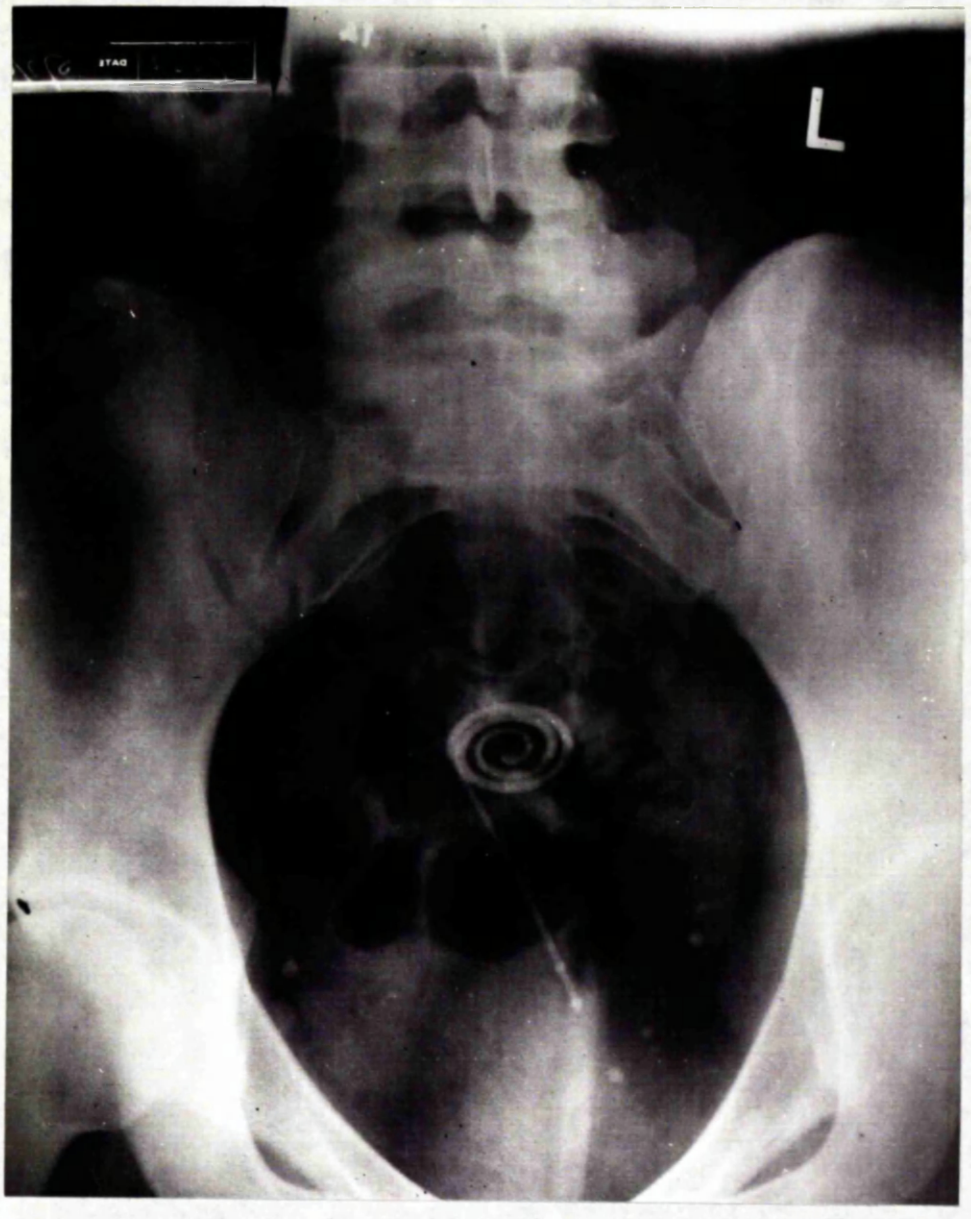

PLATE X

X-ray of Margulies spiral in the uterus

PLATE XI

X-ray of Lippes Loop in uterus

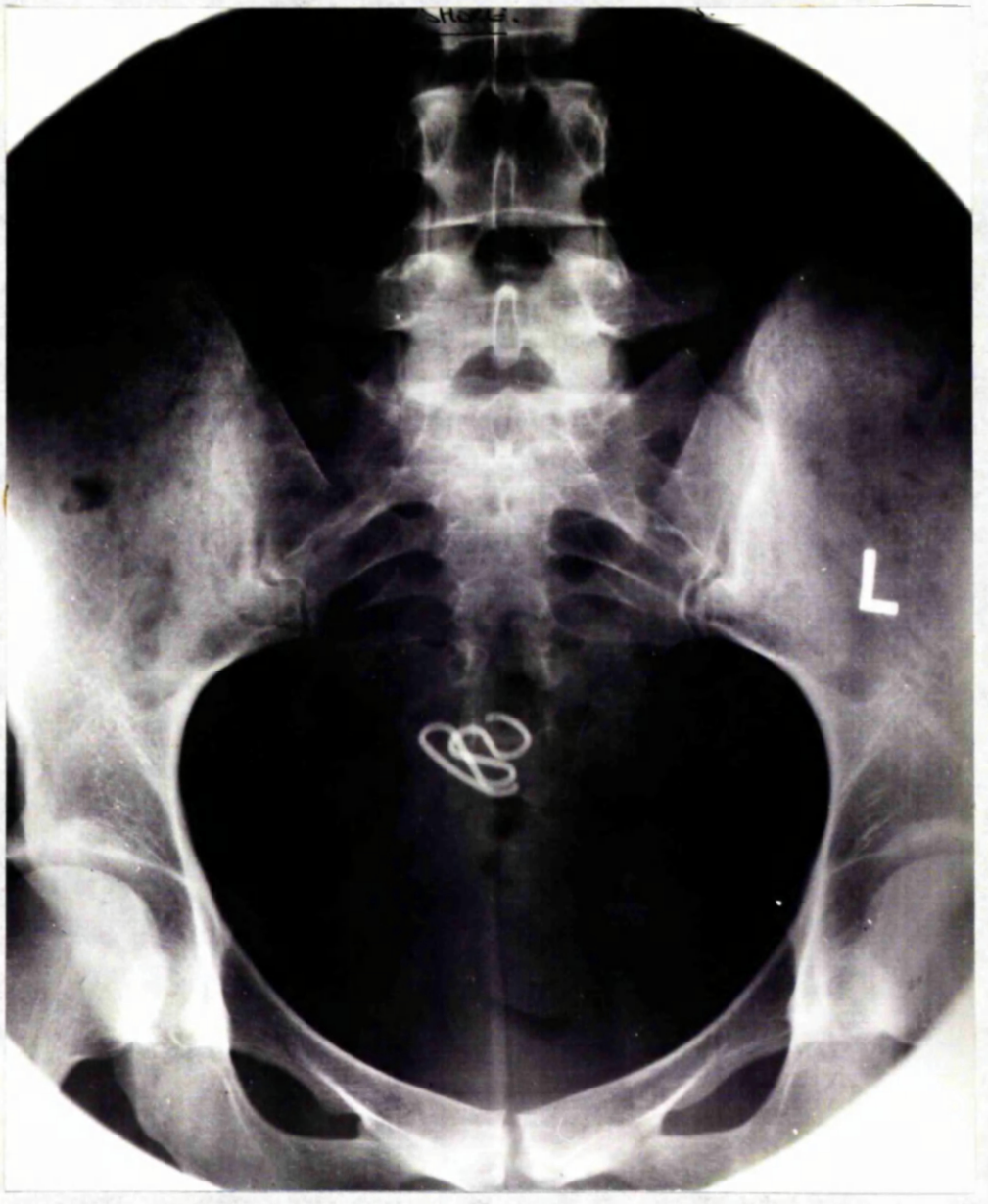

PLATE XII

X-ray of Lippes Loop in retroverted uterus;
the loop appears to be upside-down

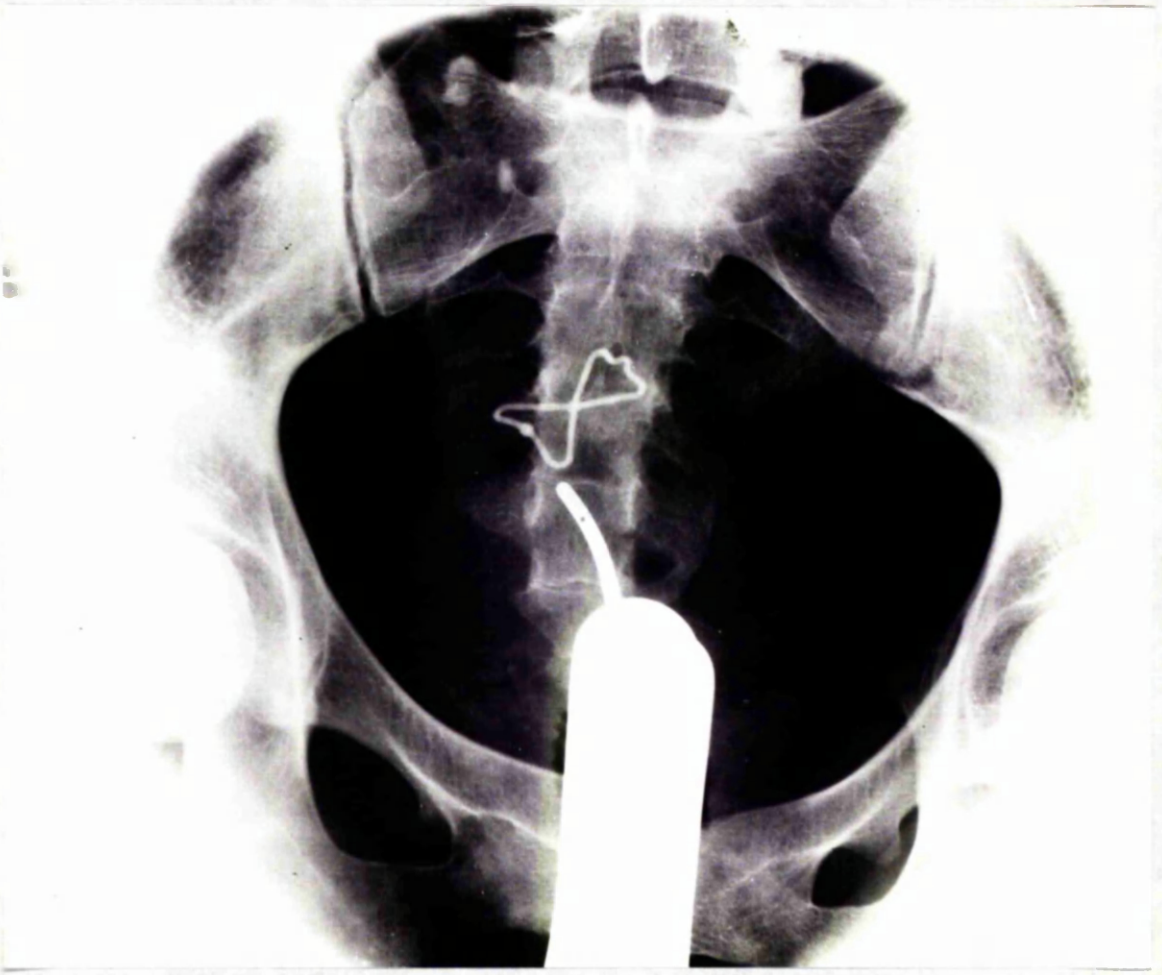

PLATE XIII.A

X-ray of Birnberg Bow in uterus
(preliminary to hysterogram)

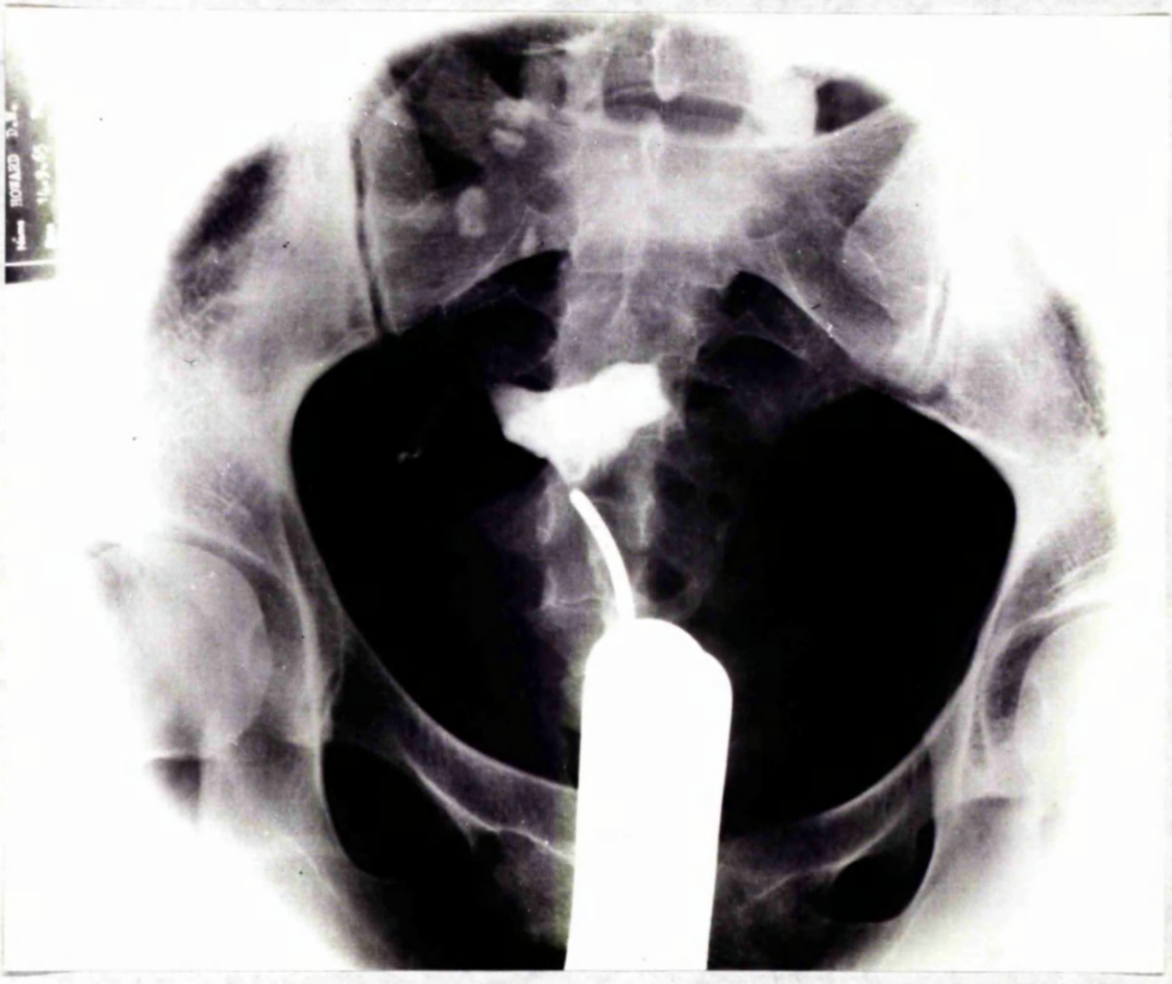

PLATE XIII.B

Same patient as Plate XIII.A after the injection of 4 ml of 45% Urografin. The uterine cavity is outlined and the bow can just be seen lying obliquely in the uterus

(The two films - XIII.A and XIII.B - would, in practice, be examined superimposed on each other)

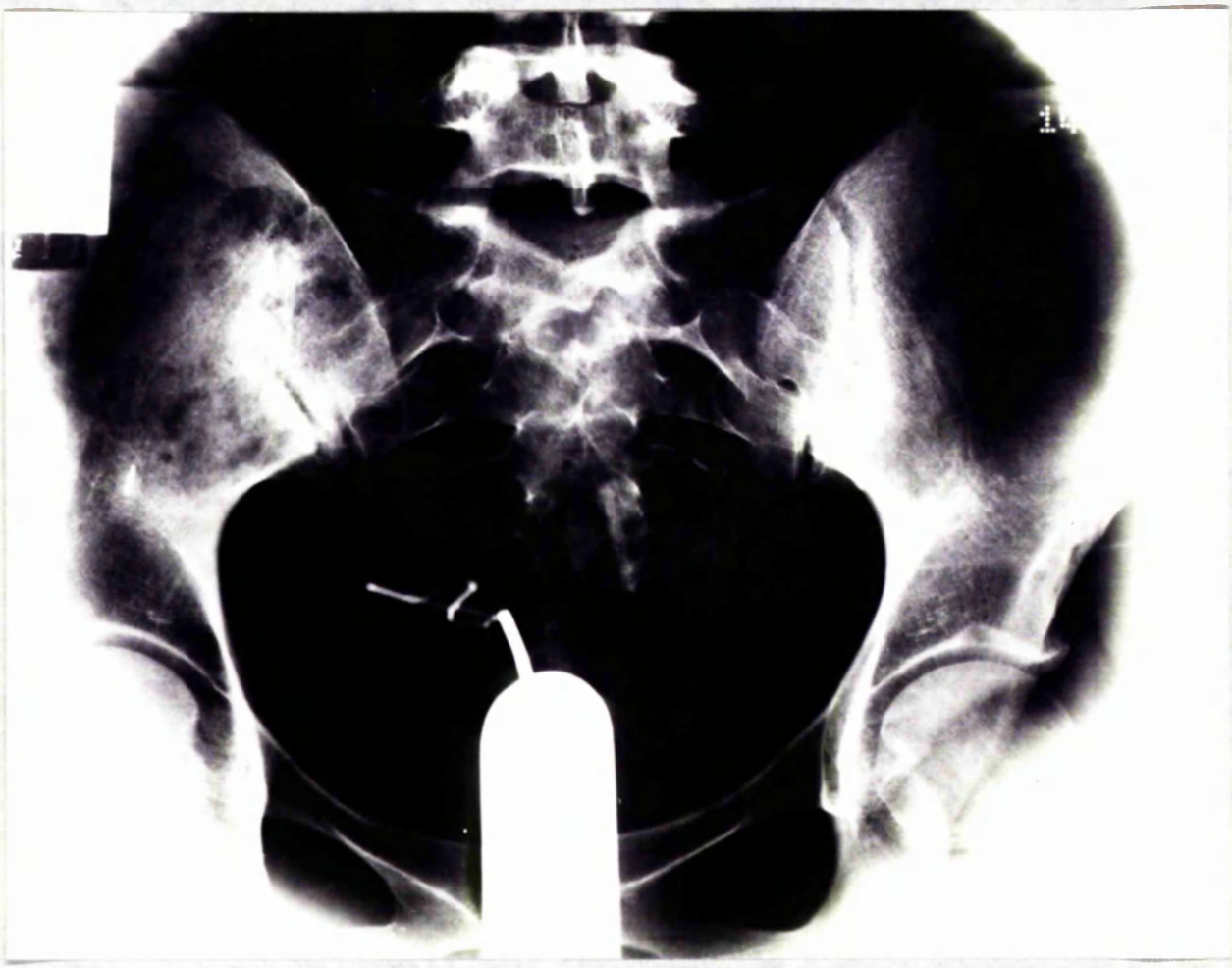

PLATE XIV.A

Another hysterogram of a Birnberg Bow, the uterus being drawn over to the right. This patient had previously expelled a Lippes Loop C

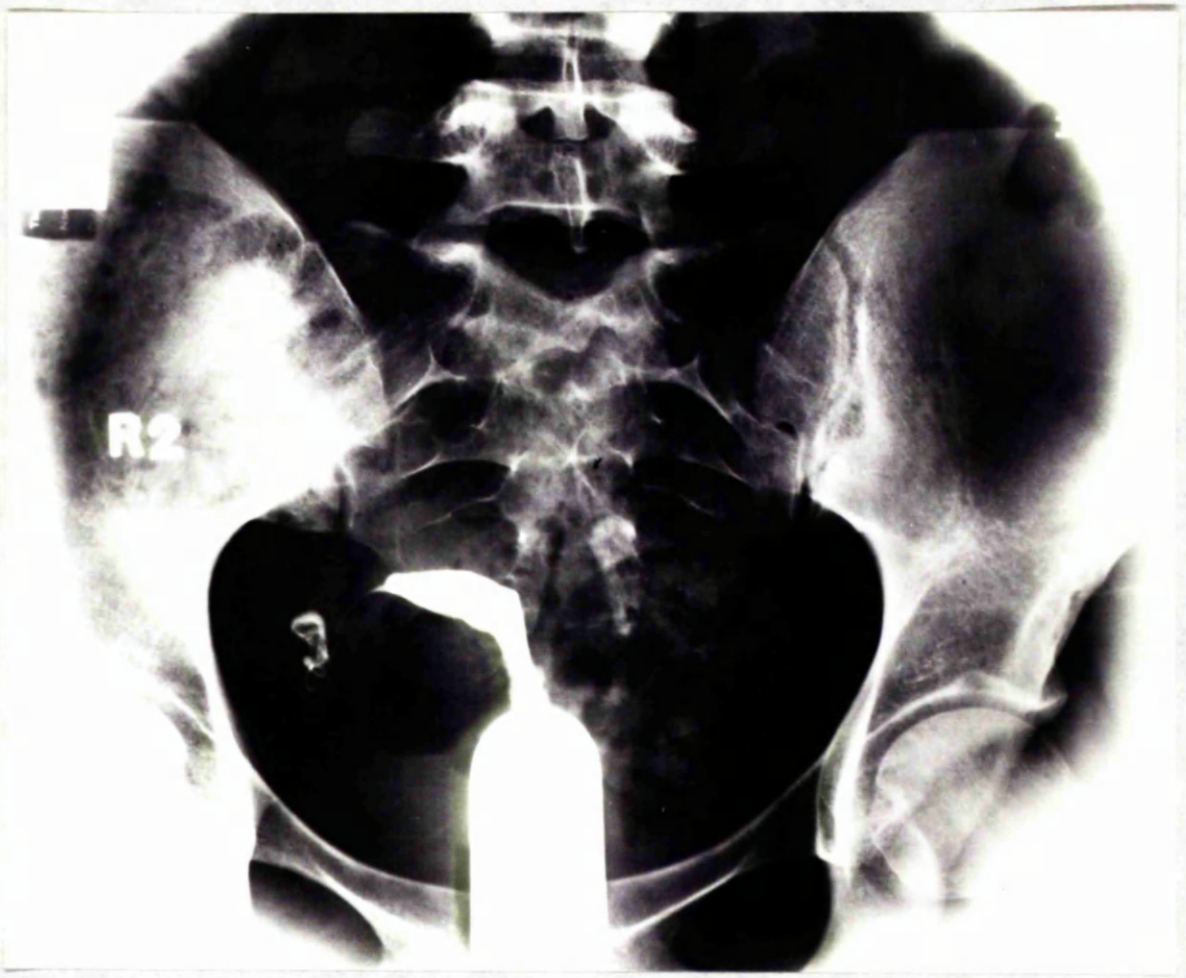

PLATE XIV.B

Same plate as XIV.A after the injection of 4 ml of 45% Urografin. Uterine cavity is outlined, but bow is obscured by opaque medium

which they had expelled. One patient was found to have a very patulous internal os. All these patients subsequently retained a Birnberg bow 6 without difficulty. Mazar et al. (1967) in ten cases of confirmed expulsion found an arcuate uterus in three and a sub-septate uterus in one. Nothing abnormal was noted in their other six patients. (See plates).

Reinsertion after expulsion

Expulsion of an IUD is likely to be followed by conception, so that every care should be taken to ensure that the patient is not pregnant before fitting another device. The majority of intelligent women who are aware that they have expelled their IUD will commence other contraceptive precautions, but the expulsion of the IUD to the exterior may take some time. Conception may occur when the IUD lies in the cervical canal or vagina.

If the patient is seen during or just after menstruation, X-ray (if necessary) and refitting can be carried out at once; on the other hand if she is in the pre-menstrual phase X-ray examination and fitting should be postponed until after the onset of the next period. There are, however, exceptions to this general rule and each case should receive individual consideration.

Type of device refitted

Of the 49 patients in the series who expelled their IUDs, 11 did not wish to be refitted and were instructed in other methods of

contraception. Five patients were pregnant. Only one patient in this series proved to be pregnant at the time of fitting or re-fitting. The device was fitted 10 weeks after the birth of her second baby in two years during the premenstrual phase and she was probably already pregnant as she expelled the loop with an early abortion five weeks later. The patient was refitted with another loop C one week later, but this was expelled. However, a loop D inserted four weeks after the abortion has been satisfactorily retained for 16 months.

In addition to this patient, 33 other patients were refitted (see Table 22). Loop B was chosen in three cases, one after expulsion of loop A in a patient who had had no children, but one abortion, and two in patients previously fitted with loop C who were thought to have small uterine cavities (unfortunately one of these patients became pregnant, but whether the device had once again been expelled is not known). Loop C was refitted in 15 women but was expelled again by 6. Loop D was fitted five times with one expulsion. Bow 3 was fitted in one case after expulsion of loop B in a patient with a small uterus. Bow 5 was fitted in six cases, with one expulsion. This was the only bow which was expelled. Expulsion occurred after 10 weeks amenorrhoea, during heavy bleeding in a woman with previously irregular periods; she may well have had an abortion. Bow 6 was fitted twice after expulsion of loop C. One patient was fitted with a spiral after expulsion of loop C in the early days of the Council for the Investigation of Fertility Control trial. She had continued to retain this when seen fifteen months later.

Results of re-insertion

Of the 34 first re-insertions, fourteen patients were known to have retained the device, and six were lost to follow-up. Of the remaining fourteen patients one device was removed for personal reasons and one during a D and C for menorrhagia twelve months after refitting. Eight patients expelled the IUD, seven of these were refitted a second time. There were two pregnancies, one after unnoticed expulsion in a coloured woman of low intelligence and one with the device undetermined. There were also two ectopic pregnancies, both with the device in situ (the only ectopic pregnancies in the series). In one case the device (a bow 5) was left in the uterus and in the other the loop was removed and subsequently refitted.

Seven patients were refitted after two expulsions, three with loop D, one with bow 5 and three with bow 6. One expelled the loop D after a year and was not refitted, five are known to have retained the device for between eleven and eighteen months. One bow 6 was removed at twenty-two months as the patient wished to become pregnant - she had previously been delivered by Caesarean section. The patient fitted with a bow 5 was lost to follow-up.

Comment

As will be seen from Table 22, the incidence of complications after re-insertion of an IUD is considerably greater than after first

insertion. Although the subsequent outcome was satisfactory in 44% of refitted patients in this series, 23.5% of patients expelled the device for a second time and 12% became pregnant, two with ectopic pregnancies. After a second re-insertion 4 of 7 patients were satisfactory and a further patient was lost to observation. There is thus a reasonable expectation of a satisfactory outcome after a second re-insertion, provided a bow is used.

Tietze & Lewit (1965) reported an expulsion rate of 52.9 after re-insertion of all types of IUD, the rate for loop D (37.4) was four times that for expulsion after first fitting. On the other hand the expulsion rate for the bow (7.3) was the same after first and subsequent fittings.

Satterthwaite et al. (1965) also found the rate of expulsion after first refitting to be approximately 50%. They considered that the chance of retaining a third device was so small as to make a change of contraceptive method advisable, but suggested that a bow might be tried.

When deciding whether or not to refit a patient with an IUD after expulsion, many factors must be considered. If the woman is intelligent and capable of using other birth control methods it should be explained that the chances of re-expulsion are greater than normal in her case and the decision as to whether she should be refitted should be made by her. In dealing with patients of low intelligence

the responsibility will lie much more with the doctor, but for many patients an IUD may be the only practicable method of contraception and will be much better than no method or those which will not be used systematically. In either case it must be impressed upon the patient that she must keep a most careful watch for re-expulsion of the device.

Tietze (1965b) has shown that the larger sizes of device are, on the whole, less likely to be expelled and it seems reasonable to refit some of these patients with the largest loop. The expulsion rate with the bow is small, but the chance of perforation of the uterus is almost ten times as great with the bow as with the loop (Tietze, 1965c) (but perforation occurs mainly in puerperal women, and patients who have already expelled a device will usually be refitted some time after delivery). The pregnancy rate with the large bow is about twice as great as with the large loop (Tietze, 1965b). Insertion and removal of the bow is considerably more difficult than with the loop. The bow should therefore only be used for patients who are well relaxed and easy to examine. Women of high parity tend to be suitable and if they have a patulous internal os are often easily fitted with the largest size of bow. Because of the difficulty in removing a bow, it should not be used for patients contemplating another pregnancy within a year. If such patients cannot retain a loop other methods of contraception should be advised.

The current series suggested that if an IUD is to be fitted after two expulsions a bow 5 or 6 should always be chosen. Whether these devices should be used routinoly after first expulsion is difficult to say. Each case should be judged on its own merits.

REMOVALS

Removal rate

Of the 539 IUDs fitted for the first time 91 were removed, 58 for medical reasons and 33 for personal reasons, an overall removal rate of 14.5 per 100 woman-years of use (Table 23). The most important medical reason for removal of an IUD was bleeding - including spotting - less commonly pain, including dysmenorrhoea and other kinds of discomfort. Both these symptoms were present in some cases. The most usual personal reason for removal of the IUD was the desire for another pregnancy, but lack of confidence, fear of injury, objection by the husband or religious scruples also accounted for some requests. The largest removal rate was found with loop A (29.5 per 100 woman-years). The removal rate for the spiral was 22.2, loop C 14.4, loop D 10.1, bow 3, 9.5 and bow 5, 7.7.

In his analysis Tietze (1965b) reported that with the exception of spirals the removal rate was similar for all devices. For loop C the removal rate was similar in Tietze's series and in the current trial.

The removal rates were different among clinic, private and hospital patients. The greatest removal rate was found in private patients (23.8 per 100 woman-years) but this included all the loop A removals. In the clinic patients the rate was 14.2 and in the hospital series 11.2. The greater rate in private patients may indicate the more sophisticated woman's dislike and fear of the side effects of the

IUD, such as menorrhagia and spotting. Moreover, the indications for removal of the IUD from hospital patients tended to be more stringent since most were unable to use another contraceptive method. The proportion of removals for medical as opposed to personal reasons were similar in the clinic and private patient series, but the removals for personal reasons were very much less frequent in the hospital series where many patients were fitted because a further pregnancy was considered inadvisable on medical grounds. The large proportion of IUDs removed for medical reasons from nulliparous patients is a further indication of the unsuitability of this method of contraception for most women who have not had children.

In no case in this series was any difficulty experienced in removing the IUD. All but 10 women had the loops removed as out-patients. Among the 10 removed from in-patients, 3 were removed during curettage for bleeding, 3 during cone biopsy because of positive cervical smears, 1 during examination under anaesthesia because of a suspected ovarian cyst and 3 during treatment for pelvic inflammation. Two women had bows removed as out-patients, and another 3 as in-patients - of these three one was removed during a D & C for menorrhagia, one during the treatment of pelvic inflammatory disease and one at hysterectomy. All the 9 spirals were removed as out-patients.

Length of use and reasons for removal

Eight IUDs were removed within 24 hours of being fitted, five for

pain and shock immediately after insertion, two for pain continuing several hours after fitting and one for bleeding on the day after insertion (Table 24). The five patients whose IUDs were removed immediately after fitting were highly-strung and nervous women. They were all fitted when the IUD was a relatively new method of contraception and were probably not dealt with as confidently as they would have been when the clinic staff had had more experience with IUDs. None of these were hospital patients and all had had children.

One patient who had had a miscarriage but no children, was fitted without difficulty or pain, but developed colicky pain after her return home. The pain persisted despite pethedine and necessitated removal of the device twelve hours later. The two patients whose IUDs were removed the following day were both highly-strung and unintelligent women for whom an IUD had been advised because of repeated pregnancies. One was a Cypriot who spoke very little English. One of the removals during the first month of use for personal reasons, and one because a routine cervical smear taken when the IUD was inserted was reported positive; this patient was admitted to hospital for a cone biopsy. In the remaining case the IUD was removed because of pain and bleeding in a nulliparous patient.

Eight IUDs were removed during the period 2-5 months after insertion - 3 for medical and 5 for personal reasons. One was removed for pelvic inflammatory disease and two for bleeding. One spiral was

removed and replaced by a loop as the husband could feel the tail of the spiral. Two were removed because the patients had changed their minds and wished to become pregnant, and two for unspecified personal reasons.

Between 6 and 11 months, sixteen IUDs were removed for medical reasons, including one bow 3 fitted early in the trial for a para 8; this was replaced by a bow 5. One device was removed for pelvic infection and the remainder for bleeding. Five patients wished to have the IUDs removed in order to become pregnant or for other personal reasons.

There were eighteen removals for medical reasons during the period 12-18 months after fitting, including three cases of pelvic inflammatory disease. One patient was found to have a positive cervical smear and was admitted to hospital for curettage and cone biopsy. The remainder were removed for bleeding. Thirteen IUDs were removed for personal reasons, including nine patients who wished to become pregnant.

In the 18-23 month period, six IUDs were removed for medical reasons, three patients had menorrhagia and in two of these curettage was carried out. Two patients complained of intermenstrual bleeding: one of these - a woman of 42 wearing a bow 3 - was found to have an ovarian cyst. The surgeon removed her uterus at the operation, although it appeared normal, the bow was found in situ and the endometrium

showed no abnormality. One IUD was removed for pelvic inflammation. Four patients had their devices removed as they wished to become pregnant.

Between 24-29 months, four IUDs were removed for medical reasons, three for menorrhagia and one because the patient was found to have a positive smear necessitating a curettage and cone biopsy. Two patients had their IUDs removed as they wished to become pregnant.

Between 30-35 months two IUDs were removed for personal reasons. One spiral was removed for menorrhagia after 36 months of use.

In the series the number of removals for both personal and medical reasons was greatest during the period 6-17 months. Most patients expect to get heavy periods for the first few months of use but if these do not diminish within six months, removal of the device may be necessary; the majority of medical removals were for this reason. Most removals for personal reasons were because another pregnancy was desired. As mentioned above, no patient was advised to use an IUD if she wished to begin another pregnancy within a year, but a few changed their minds before this. The greatest number of removals because of desire for a further pregnancy occurred between 12-17 months and most later removals were for this reason. The reasons for removal after first insertion are shown in Table 25.

Removals for bleeding

Thirty-four IUDs were removed because of menorrhagia. Six of

these patients also complained of dysmenorrhoea. Four IUDs were removed because of intermenstrual spotting; one patient aged 42 who complained of this symptom was found to have an ovarian cyst and hysterectomy was performed. The endometrium showed no abnormality.

Intermenstrual bleeding

Spotting, pre- or post-menstrual or at mid-cycle is by no means uncommon in patients wearing IUDs. If looked for, endometrial cells are frequently found in the vaginal smears of women wearing these devices, even though they may not complain of any intermenstrual bleeding. It is difficult to decide which patients with intermenstrual spotting should have the IUD removed, as many are very reluctant for this to be done. Another difficulty is in deciding if removal is indicated in patients over 40 (9.2% in this series), as there is the danger of missing an early endometrial carcinoma. Endometrial carcinoma has never been described in a patient wearing an IUD (even a Grafenberg ring) and it is thought that endometrial carcinoma is due to hormonal imbalance rather than irritation (Taylor, 1965). When spotting was regular and confined to the pre- or post-menstrual phase or to the time of ovulation and there were periods completely free from bleeding, the patients were carefully watched. Vaginal and cervical smears were taken for cytological examination at yearly intervals. Any patient who complained of continuous spotting had the device removed as well as having smears done. In every case symptoms ceased when the device was removed.

Menorrhagia

As mentioned previously, the first period after insertion of an IUD is nearly always very heavy and patients were warned to arrange to take things quietly at this time. When subsequent periods were very heavy some improvement opuld be expected from norethisterone 5 mg. twice daily from the 15th to the 25th day of the cycle. Some patients found that the menorrhagia recurred after this treatment was stopped, but others received permanent benefit.

Patients who were already taking oral contraceptives when fitted with an IUD were advised to continue to take these for one or two cycles. Sometimes, however, immediate cessation of oral contraception was necessary on medical grounds.

Haemoglobin estimations were not done as a routine, but any patient who looked pale or complained of feeling 'washed out' after her period was advised to take iron. In view of the report by Zadeh et al. (1967) it would seem wise to prescribe iron for some months to any woman fitted with an IUD, and to check the haemoglobin at return visits if facilities are available.

Menorrhagia and/or intermenstrual bleeding may be a symptom of low grade pelvic infection and should be suspected when associated with pelvic pain or discomfort or low backache. This is especially so if examination reveals pelvic tenderness. A course of a wide-spectrum antibiotic such as tetracyclin may be beneficial in these cases. When irregular or heavy bleeding occurs after a late period,

an early abortion may be suspected and if bleeding continues curettage may be necessary. When delay in menstruation is accompanied by spotting, especially when associated with pain, the possibility of ectopic pregnancy should be borne in mind (Denny, 1966).

Zadeh et al. (1967) studied 72 women fitted with IUDs and found that there was a progressive fall in the mean haemoglobin concentration for one year after fitting. They concluded that the majority of women wearing IUDs suffer from varying degrees of iron deficiency anaemia during the first twelve months but that there is a trend towards improvement after the IUD has been used for more than a year. The effect of the IUD is relatively more severe in those who are already anaemic or iron-depleted. In contrast to women fitted with an IUD they found that 40% of women taking oral contraceptives had a haemoglobin concentration greater than 14 g/100 ml. They conclude that the marked effect of the IUD in producing iron deficiency should be considered when giving contraceptive advice. This is especially true in developing countries where there may already be a considerable incidence of iron-deficiency anaemia.

PELVIC INFLAMMATORY DISEASE

Of the 539 patients fitted, 7 developed pelvic inflammatory disease, an incidence of 1.2 per 100 woman-years of use. Table 26 gives further particulars of these patients, 6 of whom were wearing a Lippes loop and one a Birnberg bow. All cases of pelvic inflammation occurred between 4 and 18 months of fitting the IUD. In no case was there an obvious relationship between the IUD and pelvic inflammation and it is difficult to know whether the presence of the IUD bore any relation to the development of the infection. Cases 1 and 5 were women who were promiscuous and in case 5 the tubo-ovarian mass developed immediately after an extra-marital relationship, but no evidence of venereal infection was found in any case. Case 2 suffered from recurrent pelvic pain associated with chronic enteritis, and the infection may well have been transferred from the bowel. Cultures from the vaginal vault and the IUD (after removal) were negative, but the symptoms subsided after a course of antibiotics. Case 3 was found at laparotomy to have an abscess between the uterus and bladder; the uterus, tubes and ovaries were healthy and there was no evidence of perforation of the uterus. The IUD was removed by hysterotomy.

Case 4 complained of pelvic pain and a purulent discharge. She was treated by her general practitioner with antibiotics, but the purulent discharge from the uterus did not subside until he had removed her IUD.

Case 6 complained of pelvic pain and bleeding and was found to have a tubo-ovarian mass; she was given a course of antibiotics and the condition subsided without removal of the IUD.

Case 7 complained of acute lower abdominal pain and irregular bleeding. Her temperature was 101.4 F. On pelvic examination there was acute tenderness in the fornices, but no masses were palpable. Culture of a high vaginal swab, and of the IUD which was removed, grew no pathogens. The condition subsided after two weeks' treatment in hospital with antibiotics. None of these patients has been refitted with an IUD.

Tietze et al. (1965) gives an overall incidence of pelvic inflammatory disease of 1.7 per 100 woman-years, the rate being greater with the tailed devices than with those lying entirely within the uterus. Their incidence with the Lippes loop D was 1.2. He believes that pelvic inflammation occurs more frequently among clinic than among private patients. In the current series 5 cases occurred among patients in social class II and one in a patient in social class I. In Tietze's series just over half the cases were treated successfully without removal of the IUD, whereas in the current series it was removed in all but one case. This difference may be because the majority of patients were admitted to hospitals where the gynaecologist had little experience of IUDs and considered that removal should be the first line of treatment. In Tietze's series, more than half the patients gave a history of previous pelvic infection,

but in this series there was no history of previous pelvic infection or septic abortion in any patient.

Elstein (1967) reported a much higher incidence of pelvic inflammation in women wearing IUDs, especially those with transcervical appendages. His diagnoses were made on clinical grounds and depended upon the finding of adnexal tenderness and cervical excitation pain on examination. There was rarely an increase in the sedimentation rate or a leucocytosis in these patients.

It is surprising that pelvic infection does not occur more commonly after insertion of an IUD, as the uterine cavity is contaminated by micro-organisms normally resident in the cervical canal when the IUD is pushed through it. Mishell et al., (1967) using the transfundal method, found positive cultures in the uterine cavity in every case in which an IUD had been inserted within the previous 24 hours. The incidence of positive endometrial cultures diminished rapidly thereafter and after one month the endometrial cavity was sterile in every case. The uterine cavity appears to possess a previously unsuspected capacity to deal with contamination. The proved subsequent fertility of patients who have had an IUD removed to become pregnant suggests that this transient uterine infection is unlikely to lead to tubal damage.

OVERALL COMPLICATIONS AND ACCEPTABILITY

Rate

Table 27 shows the complication rate for each 100 woman-years of use according to device. Apart from Lippes loop C the number of months of use with each device is small and the likelihood of chance variation has to be borne in mind when making comparisons between the various types.

The greatest complication rate (50.4 per 100 woman-years) occurred with loop A which, it will be recalled, was used for nulliparous patients. The next greatest rate was for loop B, but this device was used too seldom to make useful comparisons.

The Margulies Spiral was also associated with a high rate of expulsions and removals - 32 per 100 woman-years of use.

The total rate of pregnancies, expulsions and removals with loops C and D and bows 3 and 5 were much less than the other devices, ranging from 12.6 to 19.5 per 100 woman-years of use.

Months of use

Table 28 shows the total number of pregnancies, removals and expulsions according to the period elapsing since insertion. It is clear from the figures that the greatest number of patients with complications were seen during the period 12-17 months after insertion. The decline in the number of patients with complications after 12-17 months is affected by the fact that, as mentioned previously, the

proportion of patients who returned for examination declined with the period since insertion. The number is also affected by the fact that the total number of patients available for examination became less after one year.

The table also shows the relative frequency with which the three types of complication occurred at different times after insertion. It is clear that expulsions were the most common complication between one month and 2-5 months after insertion. At 6-11 months expulsions were still relatively common but removals for medical reasons were even more frequent. At 12-17 months after fitting medical removals had become the most common complication: removals for personal reasons were almost as frequent. At 18-23 and 24-29 months the frequency of pregnancy and of removals for medical and personal reasons were all relatively great.

The alterations in the relative frequency of complications reflect the tendency previously demonstrated for expulsions to occur in the early stages; later medical removals became relatively common, largely due to the instances in which the expected menorrhagia had failed to decrease. About one year, and subsequently, the tendency for patients to desire another child increases the number of removals for personal reasons. (One case of pelvic inflammatory disease which did not necessitate removal of the device has not been included in the above analysis.)

Tietze et al. (1965) in an analysis of unintended pregnancies, expulsions and removals for medical reasons reported that all these

COMPLICATIONS BY MONTH OF USE

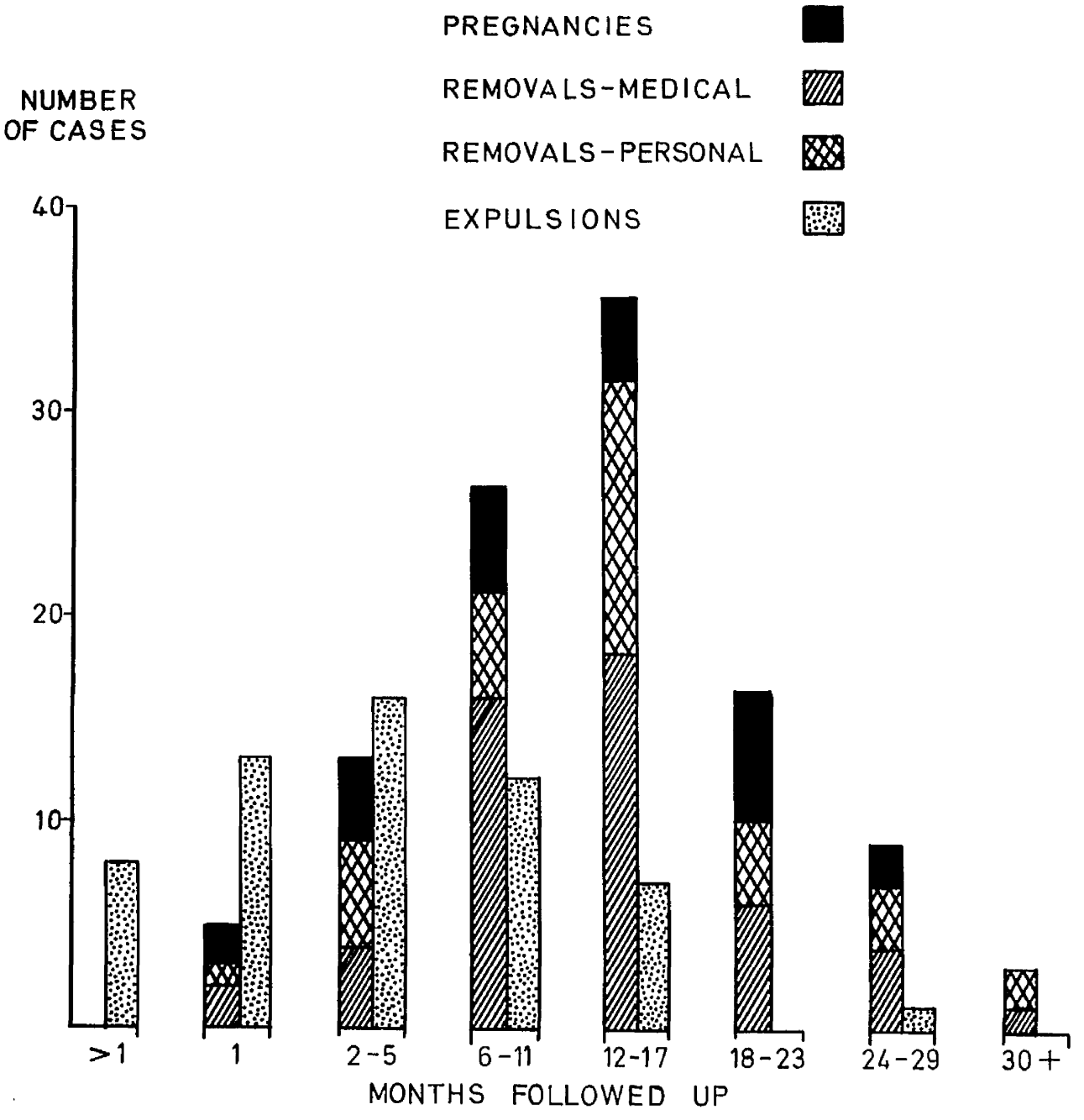

Fig.5

complications occurred less often during the second year. Removal for personal reasons, however, increase considerably during the second year as more patients wish to begin another pregnancy. These findings are in keeping with the observations in the present series.

Race

As mentioned previously 88.3% of patients fitted were of European descent, 9.5% African (including West Indians) and 2.2% Asian. The percentage of negresses expelling the IUD was more than twice that of other patients, 19.6% as compared with 8.2% and 8.4% among European and Asian patients respectively; the percentage of removals in negresses was much less than that of other patients - 7.8% as compared with 17.2% and 41.6% among European and Asian women. There is no obvious reason why the negresses in this series should have such a high expulsion-rate. Many of these women were of high parity who are usually less likely to expel the device. A high expulsion rate was found by Pike (1967) among native women in Uganda and racial differences may play a part. Some variation in expulsion and also removal rates have been observed in investigations made in different races, but variations in observation and method may be responsible. Lee & Wei (1965) in Taiwan observed an expulsion rate of 11.3% and removal rate of 22.2% with loop A; Malkani et al. (1965) in India had an expulsion rate of 8.9% and a removal rate of slightly less than this; Shin (1965) in Korea, using two sizes of loop reported an expulsion rate of 5% and a removal rate of 11.5%

Acceptability

It is not known how many patients lost to follow-up were continuing and satisfied users of the device. Calculations based on the number of patients who returned for examination are likely to be an underestimate of this proportion of satisfied users, since those with complications were more likely to return for examination. This would tend to underestimate the proportion of satisfied users observed.

Between 12 and 17 months 320 patients were seen and of these 42 had complications. When the 92 patients with complications which occurred before 12 months are added, the cumulative complications are 92 + 42. The proportion of patients with complications among the 320 patients and the 92 patients seen previously with complications is therefore $\frac{92 + 42 \times 100}{320 + 92} = 32.2\%$. By this calculation, the proportion of satisfied users is therefore 67.8%. For the reasons stated above, this is almost certainly an underestimate.

Tietze (1967) gives the rate of continuing use of loop C as 78.5% at the end of one year and 66.6% at the end of two years. Guttorn & Gjörup (1967) found 81% of patients continuing to use the loop at one year and 76% at the end of two years. Mateos-Cardano et al. (1967) in a comparative study of women from a low socio-economic background and private patients fitted with IUDs found that their effectiveness was the same in both groups, although the parity of the first group was twice as high as that of the second group. However, the acceptability was less in the second group.

REMOVAL OF IUD BECAUSE PREGNANCY IS DESIRED

Table 29 shows details of the 25 patients in this series who had their IUD removed because they wished to become pregnant. Six conceived immediately, and 5 of these were so satisfied with this method of contraception that they were refitted with another IUD approximately one year after removal of the previous one. Two conceived within six months and 4 within a year of removal of the device, one of these was refitted after delivery. Four IUDs were removed during the last 3 months of the follow-up; none of these patients has yet reported a pregnancy. One patient, aged 36, was not pregnant one year after removal of her loop. Seven patients were lost to follow-up and one patient decided against pregnancy after the device was removed, and took oral contraceptives. Ten women had normal confinements at term, and one patient - the only nullipara - miscarried at 11 weeks. One patient is awaiting confinement. These findings are summarized in Table 30.

Several patients had some difficulty in deciding to try to become pregnant again and when the IUD was removed asked to be refitted with a cap to give them a little longer to consider the matter. One of these conceived at once and was subsequently fitted with another loop. Another reported that she was not pregnant one year later. Women who are ambivalent about another pregnancy often seem to choose a contraceptive method which can be discontinued more easily than IUDs when they have finally made up their mind.

Tietze & Lewit (1965) have shown that in 109 patients from whom an IUD was removed because the couple wanted a child, about 70% of women

conceived within 6 months and 90% within a year. A similar rate to that observed within the general population. They do not consider that the wearing of an IUD results in reduced fertility after its removal. Lay (1965) removed the IUDs from 35 patients; half of these became pregnant in three months and none took longer than 9 months. Brooks & Horne (1966) reported easy conception in 3 of their patients. Oppenheimer (1962) said that he had seen many patients wearing his silkworm-gut ring on and off for many years who had planned their children according to their liking. Not one had to be treated for sterility and all of them became pregnant within three months after removal of the ring. Hall & Stone (1962) reported 13 cases of pregnancy which occurred readily after removal of the steel ring. Satterthwaite et al. (1965) reported 84 pregnancies within an average of 6 months after removal of various types of IUD. Eight of these women returned for re-insertion of the device post-partum.

Thus it appears that an IUD does not usually reduce fertility. It is interesting that it should be so effective as a contraceptive in women whose fertility is so high that they conceive immediately after its removal.

NULLIPAROUS PATIENTS FITTED WITH IUDs

The fitting of nulliparous patients with IUDs is not recommended by the Medical Advisory Council of the Family Planning Association. They consider that fitting may be difficult and accompanied by complications. Moreover, should pelvic infection occur this might be followed by infertility, which would be especially undesirable in a woman who had not already borne children. Frith (1966) found that only about half her nulliparous patients could be successfully fitted. Lay (1965) reported on the use of loop A for nulliparous patients. He found that there was usually pain on insertion and that over half had to have the IUD removed for pain and/or bleeding.

In the present study, 34 nulliparous women (13 of whom had had one previous abortion) were fitted with IUDs. Five were fitted for medical reasons (4 psychiatric and one with a history of carcinoma of the thyroid), and 29 because they had found other contraceptive methods unsatisfactory. The latter included two women, who, because of partial impotence in their husbands, were unable to use conventional contraceptive methods and for whom oral contraceptives were unsuitable. The disadvantages of the IUD were carefully explained to all these patients before they were fitted.

Insertion of the smallest devices did not seem more difficult than in many multiparae. This was especially so for some multiparae who had not had a child for many years or who had been on oral contraceptives for some time; in many cases oral contraceptives seem

to produce some rigidity of the cervical canal. In two very nervous private patients the IUD was inserted under general anaesthesia. The psychiatric patients were not always very co-operative but the fitting itself was not difficult once their confidence had been gained. Some nulliparous patients experienced more pain than others in the days following insertion of the device; in one this was so severe that removal became necessary after 12 hours.

Loop A was used for 27 patients, loop B for 4 patients, loop C for one and bow 3 for 2.

The total pregnancy rate for loop A was 8.4 per 100 woman-years as compared with 3.4 for loop C in parous patients. The expulsion rate for loop A was 21.1 per 100 woman-years as compared with 7.6 for loop C. The removal rate of loop A for medical reasons was especially great - 21.1 as compared with 8.5 for loop C. The removal rate was 29.5 for loop A and 14.4 for loop C. The findings thus suggest that complications are much more likely in nulliparous as compared with multiparous patients.

PREVIOUS CAESAREAN SECTION

Thirty patients who had previously had Caesarean sections were fitted with IUDs: 6 out of 216 patients at North Kensington (2.7%), 7 of 170 private patients (4.1%) and 17 of the 153 hospital patients (11.1%). Nineteen had had one Caesarean, 8 two Caesareans, and 3 three Caesareans. Fitting was only carried out if the uterus was well involuted and anteverted and if the sound passed easily into its cavity. There was no difficulty in fitting the IUD in any of these cases. Loop C was used for 28 patients; the spiral and bow 5 were each used once during the C.I.F.C. trial at North Kensington clinic.

All but 5 patients have been seen at least once since they were fitted and some have been followed up for as long as 2 years.

Two patients, each of whom had had one Caesarean section, expelled their loop C within a month of fitting; each was refitted with a loop C and again expelled the loop within a month. After both were refitted with bow 6, one retained the device without incident for 18 months and then had it removed as she wished to become pregnant again. The other patient was still wearing the bow satisfactorily 12 months after fitting. One patient who had had 3 Caesarean sections expelled a loop C 4 months after fitting during a late period. She did not wish to continue with this method of contraception.

Removal of the IUD for bleeding or other complication was not necessary in any of these patients. There were no pregnancies.

Loop C would seem to be the most suitable IUD to choose for women who have had Caesarean sections; it is easily inserted and is more flexible and therefore less likely to cause damage to the uterine wall than loop D. The patient fitted with a Margulies spiral during the clinical trial had had 8 children (one by Caesarean section for placenta praevia). Six months after fitting all appeared to be well with her, she was then lost to follow-up. The patient fitted with bow 5 had had 9 children (one by Caesarean section for prolapsed cord) and was well when seen 19 months after fitting.

The possibility of perforation of the uterus must always be borne in mind when fitting an IUD for a patient who already has a scar in the uterine wall. There are few previous reports of the fitting of IUDs in women who have had a previous Caesarean section. The incidence of perforation of the uterus is given by Tietze (1965c) as 0.6 per 1000 insertions for loops and spirals and 5.1 for bows. No note is made of whether any of these patients had had Caesarean section. Mills (1967b) reports 4 cases of perforation of the uterus in his series of 1300 insertions; one of these occurred in a woman with a retroverted uterus who had had one Caesarean section, she had been fitted with a Lippes loop.

Hysterograms were performed on the two patients who were fitted with bow 6, after having twice expelled the loop. This examination confirmed that the bow was lying snugly in the uterine cavity. One was removed a year later without difficulty.

No case of perforation is known to have occurred in this series and none of these patients has become pregnant.

When a patient presents herself at a contraceptive clinic with a history of Caesarean section, the cap or oral contraceptive may well be a better choice than an IUD. Neither the cap nor oral contraceptive, however, may be suitable because of the socio-economic status and intelligence of the patient. In instances in which the Caesarean was done for severe pre-eclampsia or other disease, the underlying medical condition might contra-indicate the use of oral contraceptives. If the IUD is the only possible method, the fitting should be done by a doctor with special skill and considerable gynaecological experience.

Three patients in this series had 8 or 9 children and tubal ligation at the time of Caesarean section might have been preferable. All too often the probability of future contraception is not considered during pregnancy in these patients; should emergency Caesarean section become necessary there may not be time to discuss the question of tubal ligation.

Finally, there appears to be no indication in this small series that IUDs are unsuitable for patients who have had Caesarean sections.

CERVICAL CYTOLOGY

Cervical and vaginal smears were taken for cytological examination from 461 of the 539 patients at their first attendance. The cervical smears were taken by the Ayre scrape technique. Originally only those patients of over 25 had a smear taken, but following MacGregor's report (1966) all those who had had two or more children or who came from poor socio-economic backgrounds, even if under this age, were also included. Smears could not be taken from a few patients at their first visit if they were menstruating, but in the majority of cases this was done at their return visit after the IUD had been fitted. Routine repeat smears were taken whenever possible after the IUD had been worn for a year.

Smears taken from the vaginal pool are of particular interest in patients wearing IUDs, as in a proportion of cases endometrial cells are present. The appearance of some of these cells in patients in the present series was unusual. A study of vaginal smears and of endometrial cells obtained by aspiration in patients wearing IUDs is now in progress.

Results of smears taken at first visit

Of the 461 smears taken at the first visit, 458 were reported negative for malignant cells. Two showing atypical cells were reported negative when repeated three months later. One smear was reported positive and the patient was admitted to hospital for a curettage and

cone biopsy. This showed no evidence of malignancy and she was refitted with a Lippes loop and has been followed up for 30 months. Subsequent smears have been reported negative.

Results of smears taken after one year or more

Smears were taken from 305 patients after they had worn an IUD for a year or longer; all but two of these were reported negative. One patients was found to have a positive smear after wearing a Lippes loop for 13 months and a cone biopsy showed a very small carcinoma in situ. Review of the smear taken at her first visit showed a few atypical cells, which had originally been thought to be inflammatory in origin. This experience illustrates the advantage of repeat smears: Egerton (1967) considers that the second smear may be used to confirm the first. If both are negative it is probably not necessary to repeat the test for another 3 years in the absence of gynaecological symptoms. The patient mentioned above was not refitted with an IUD for personal reasons and smears taken at 6 and 12 months after the biopsy were both satisfactory.

The second patient was found to have a positive smear after wearing a Lippes loop for 25 months. A cone biopsy showed a small area of dysplasia. Unfortunately a routine smear had not been taken at her first visit as she was then only 25. She was subsequently refitted with a Lippes loop and will return for repeat smears at 6-monthly intervals.

IUDs after previously positive smears

Three patients were referred for the fitting of IUDs after positive smears had been diagnosed while they were taking oral contraceptives. Cone biopsy in two of these showed no evidence of malignancy, the third was found to have a small carcinoma in situ. The two former patients have been followed up for 15 and 33 months respectively and repeated smears have been negative. The third patient has been followed up for 15 months and her smears are also satisfactory.

Fitting of an IUD after a cone biopsy may not be easy if the cervical canal is stenosed by scar tissue, and if much of the cervix has been removed there may be some difficulty in retaining the device. Three patients were easily fitted with Lippes loops. One of these patients experienced repeated expulsion of the IUD; she was a woman of low intelligence who had had a pre-frontal leucotomy and was unable to use any other method of contraception. It was thought that despite the risk of another expulsion it was preferable to fit an IUD rather than leave her unprotected.

Jeffcoate (1966) gives the incidence of carcinoma in situ as being 4-5 in every 1000 apparently healthy women over the age of 25. MacGregor (1967) showed a detection rate of 0.7%. The three positive smears found on routine examination - which on further investigation showed one carcinoma in situ and one dysplasia - fall within these limits.

Anxiety has been expressed that intra-uterine devices might have a carcinogenic effect, possibly because of mechanical irritation

or as the result of cellular reaction to the constituents of the device. Ayre (1965 & 1966) warned against the use of intra-uterine devices composed of polyethylene. He reported that with polyethylene there was a rapid development of endometrial hyperplasia with or without cervical dysplasia in about 16% of cases. Ayre thought that this might be due either to the polyethylene or to the barium salts it contained, and noted that polyethylene implants in animals had been found to be carcinogenic. Ayre based these opinions on the findings in a small group of 19 patients who were all fitted with the Margulies spiral. The endometrial specimens were obtained by brushing and not by biopsy. It is important to appreciate that Ayre's findings have not been confirmed by other workers.

Taylor (1965) stated that no case of endometrial carcinoma had been reported in association with an IUD, and noted that endometrial carcinoma rarely occurred before the menopause. It was unlikely to be due to irritation, and had a constitutional - perhaps endocrine - basis Endometrial carcinoma was thus unlikely to be caused by an IUD. He considered that on general grounds it seemed probable that the cyclical shedding of the endometrium would prevent changes due to prolonged pressure and irritation.

Carcinoma of the cervix was not found by Grafenberg (1930), Oppenheimer (1959) or Hall & Stone (1962) who observed patients with IUDs over long periods. Ishihama (1959) reported one case of squamous carcinoma of the cervix diagnosed one year after insertion of an Ota ring,

but this did not pass through the internal os and bore no relation to the ring. Oppenheimer (1959) found no case of carcinoma (cervix or corpus) in 1016 patients fitted with a Grafenberg ring, although some had worn it from 10 to 20 years. Ishihama & Kagabu (1965) in routine screening for carcinoma of the cervix in 1553 women in Japan found that 72 of these had been fitted with an IUD 1-10 years previously. Most had been fitted three years before examination. No positive smears were found in patients wearing an IUD; 2.8% had class III smears but their biopsies were negative. In the women not fitted with IUDs 6.3% had class III smears and 0.5% class IV smears, among whom 8 cases of carcinoma - one in situ - were found.

Lee & Wei (1965) examined 1719 women before insertion of an IUD and found 2 cases of carcinoma in situ. They re-examined these patients annually and in 1087 repeat smears taken from 1301 women, none was positive. Chun & Chung (1965) examined 516 patients before insertion of a Lippes loop and again after nine months and found one case of carcinoma in situ in each series. Lippes (1965) in a series of 2730 smears in a two-year follow-up of patients wearing his loop found that the incidence of positive smears did not exceed that anticipated from the accepted norm. Richart & Barron (1967) made a prospective study of two groups of patients with cervical dysplasia. There were 221 controls and 114 wearing IUDs; they concluded that there was no evidence that the IUD increases the rate of progression from dysplasia to carcinoma in situ.

These studies do not so far indicate that the wearing of an intra-uterine device increases the risk of malignancy, but as MacGregor (1967) has pointed out, it may take 20 years for a clinical carcinoma to develop. It certainly seems desirable to continue to study the cytology of women wearing IUDs for many more years.

MODE OF ACTION

Since Grafenberg's time there has been speculation as to the mode of action of IUDs, but despite investigation and extensive clinical experience the method by which an IUD prevents conception is not yet understood.

Early abortion

Early abortion has been suggested as a possible mechanism, but no supporting clinical or pathological evidence of this has been reported. If the mechanism depended upon dislodgment of the implanted ovum longer menstrual cycles would be expected; in fact the menstrual cycles of women wearing IUDs are more often shorter rather than longer than previously.

Fertilization

An IUD does not appear to interfere with sperm migration. Malkani & Sujan-Tejuja (1964) found motile sperm round the IUD and in the Fallopian tubes of four women wearing IUDs who were operated on within 24 hours after coitus.

Bonney & Cooper (1965) recovered ova from the Fallopian tubes of two women wearing Margulies' spirals; one of these was fertilized and showed two pronuclei and the other was not fertilized. An IUD removed on the 16th day of the cycle was followed by pregnancy, although other contraceptive methods were used after its removal, (Hill, 1967). It was therefore assumed that a fertilized ovum was in the tube at the time of removal and was able to implant in the uterus after the removal of the IUD.

Mechanical obstruction

Siegler & Hellman (1964) found no mechanical obstruction to the Fallopian tubes in 4 patients wearing Margulies spirals; tubal insufflation gave a normal kymograph and X-ray appearances were within normal limits. On the other hand Mazar et al. (1967) in a hysterographic study found bilateral tubal occlusion in 44% of 100 patients wearing Lippes loops and suggested that cornual spasm may contribute to the mechanism of their action.

Uterine and tubal motility

It has been suggested that IUDs might act by interfering with the normal motility of the tubes and uterus. The low prevalence of ectopic pregnancy (less than 1/10 of the frequency among women not using contraceptives) is in favour of the IUD having some action on the tubes as well as the uterus, (Tietze & Lewit, 1965).

Bengtsson & Moawad (1966) investigated myometrial activity before and after the insertion of a Lippes loop. They found an onset of pre-labour-like activity in the cycle (the 19th instead of the 22nd day) in a patient wearing a loop. They considered that this activity might coincide with the time of implantation of the ovum and disturb or prevent this. Mastroianni et al. (1965) found evidence of altered tubal transfer of the ovum in monkeys. They suggested that the IUD acts by reducing the time taken by the ovum to pass through the tubes from three or four days to one day, and that it would be too immature to implant itself when it reached the uterine cavity.

Alteration in the uterine lumen

Rozin et al. (1967) in an X-ray study of the uterus after the injection of radio-opaque medium in 30 women, found that the capacity of the uterine cavity increased after the insertion of a loop and suggested that with the IUD in situ, the uterus is a hollow organ with separation of the normally opposed inner walls of its cavity. They suggest that this may lead to lack of contact between the blastocyst and the developing endometrium and its secretion during the 2-3 days before implantation takes place, with consequent destruction of the blastocyst. Potts et al. (1967) also suggested that alteration in the shape of the lumen of the uterine cavity, with separation of the sides, might play some part in the contraceptive action of the IUD.

Endometrial reaction

Grafenberg (1930) thought that the contraceptive action of his ring might be due to some physico-chemical change in the uterine secretions. Although with Robert Meyer he found no evidence of chronic inflammation of the endometrium, he did observe that the premenstrual endometrium appeared to be more active than normal. He regarded this activity as a hyperdecidual reaction to a foreign body. Wilson et al. (1965) described histological changes in the endometrium, especially the stroma, in women wearing spirals. These changes included an increase in tissue fluid and alterations in the vascular pattern. They found no marked inflammatory reaction, but thought that the histological

dating of the endometrium in women fitted with spirals lagged behind the normal cycle. Hall et al. (1965) made a very full investigation of the endometrium of 100 women who had been wearing stainless steel rings for up to 15 months. Their material consisted of endometrial biopsies before and after insertion of the ring in 91 women and 10 hysterectomy specimens examined with the ring in situ. They found no evidence of inflammatory changes or foreign body reaction, nor was there evidence of infection or of necrosis at the points of contact. There appeared to be no deviation in the typical cyclical changes in the endometrium and no alteration in the degree of progestational change. They found no evidence of pregnancy or abortion.

Buckle & Barnett (1966) examined the uterine histopathology in 8 patients who had worn plastic loops for between 5 and 8 months: their hysterectomy specimens showed mild surface inflammatory reaction in the endometrium, but no changes in the myometrium. Curettage material showed few features worthy of note and minimal tissue reaction microscopically. Maximum changes were found at the site of pressure of the device. They conclude that short-term studies show no convincing evidence of local reaction to the presence of plastic devices.

Potts et al. (1967) made a light and electron-microscope study of cells in contact with IUDs. They found no morphological changes in the ultrastructure of endometrial cells which might render them unsuitable to receive an implanting ovum. They also reported that the IUD caused

depression of the underlying endometrium, but only very rarely was this broken. The mechanical damage to the endometrium occurred over only very limited areas, but there was an accumulation of cells and extra cellular material in the uterine lumen which they thought might play some part in the contraceptive action of the IUD.

Abrams & Spritzer (1966) studied the endometrial cytology of 50 patients wearing plastic IUDs, by aspirating endometrial cells from the uterine cavity. They also examined cells adherent to IUDs which had been removed. They found that the IUD does not interfere with the cyclical endometrial response and found no evidence of inflammatory alteration.

Endometrial biopsies were not carried out in this series, since little further information of practical value could be gained in this way. It is not often possible to take a satisfactory endometrial biopsy with an IUD in situ and it seems unethical to remove an IUD for the purpose of taking a biopsy. The first few weeks of use after replacement are frequently accompanied by bleeding and any intra-uterine manipulation of this kind tends to increase the risk of infection. Endometrial aspiration would seem preferable to endometrial biopsy as it can be carried out without interfering with the fit of the IUD.

When all the above considerations are taken into account, there seems to be no evidence that the contraceptive action of an IUD is due to mechanical obstruction to the passage of either the sperm or the

ovum. Although changes in the endometrium are found in a small proportion of women wearing IUDs, such changes do not seem to occur with sufficient regularity to explain the efficacy with which IUDs prevent pregnancy. There is no evidence that IUDs cause repeated abortion by dislodging an early ovum which has already implanted, nor does systematic observation suggest that the presence of an IUD upsets the mechanism of ovulation. The endometrium and vaginal epithelium continue their normal cyclical changes and ova have been found in the Fallopian tubes in women wearing IUDs. Moreover, an IUD does not seem to prevent fertilisation of the ovum.

It is tempting to assume that the presence of an IUD interferes in some way with the delicate mechanism of ovum transport and implantation. Some evidence that the tubal hypermotility theory may be applicable to humans is furnished by the fact that ectopic pregnancy occurs with less than 1/10 of the expected frequency in women wearing IUDs. But this theory remains speculative at the present time.

DISCUSSION

The purpose of this investigation was to determine whether intra-uterine devices have a place in contraceptive practice in this country, and if so the advantages and disadvantages to their use. These questions must be considered in relation to the needs of those who seek contraceptive advice.

From this point of view the patients who consulted the author either at the clinic, privately or at hospital, could all be included in one of three groups:-

1. Young women who were recently married or soon to be married and wished to postpone pregnancy for a few years for personal reasons.

2. Married women who had already had one or more children and wished to space the intervals between births or who felt that their family was complete. Some, though not all, of these patients had used contraceptive measures previously and sought advice because they had found their previous birth control methods to be unsafe or unsatisfactory.

3. Those who had been persuaded to attend, or even brought to the clinic because a further pregnancy was inadvisable for medical reasons, or because of grande multiparity, often associated with low intelligence and a poor socio-economic background.

The perfect contraceptive to suit all types of patient has yet to be found. It should be harmless to health, effective and aesthetically acceptable to both partners. It should be easy to use and its action readily reversible.

In considering the most suitable contraceptive, the doctor has to choose between three main methods: mechanical barriers such as a sheath or a cap used with a spermicidal cream or jelly, oral contraceptives, or an intra-uterine device. Each of these methods has advantages and disadvantages which have to be taken into account when the needs of each patient are considered. The sheath is still probably the most popular of contraceptives as it is simple to use and its mode of action can be readily understood by all. The cap, on the other hand, must be fitted in the first place by a doctor or midwife and the patient carefully instructed in its use. The cap was the method advised almost exclusively in family planning clinics from their beginning in the 1920s until oral contraceptives were approved in 1961 and the IUD in 1965.

The sheath or the cap are harmless to health, and, when used conscientiously and correctly, are very effective. If this method is chosen the majority of unplanned pregnancies are likely to occur from a failure to use the sheath or cap consistently. Failure with the cap may occur, however, if it does not fit properly or is wrongly inserted. The type and size requires to be correctly chosen in the first place and its fit checked regularly, particularly after a few months of marriage or after childbirth or pelvic operation. Moreover, it is not always possible to find a cap that is a good fit for a patient who has a prolapse or who has had a pelvic floor repair. All patients must be most carefully instructed in the use of the cap and it is

essential to make sure that they really understand the technique of its use. Some men find it impossible to use a sheath and some women to use a cap. Many find that the premeditation required is cold-blooded and distasteful, and others consider these methods unaesthetic. Neither method is entirely suitable for couples who are inclined to be careless and the use of the cap requires a degree of intelligence not present in all patients.

Oral contraceptives are the most effective form of birth control. One pill taken daily for 21 days, followed by one week without medication ensures virtual sterility, and fertility is restored within a few weeks after the cessation of medication. The effectiveness of oral contraception makes a strong appeal to both doctors and patients which tends to overshadow consideration of its disadvantages. On the other hand many doctors are concerned about the advisability of prescribing hormone preparations to young and healthy women for periods of many years. This is especially so when the matter is only one of personal convenience. It has recently been shown (Inman & Vessey, 1968) that 1.5 deaths in every 100,000 women between the ages of 20-34 and 3.4 deaths in women aged 35-44 can be attributed each year to the use of oral contraceptives. Moreover, thrombosis and embolism requiring admission to hospital occurs nine times more frequently in women taking the pill. Apart from the serious complications, many women using oral contraception suffer from mild side-effects including lassitude, headache, weight gain, and loss

of libido, though it is also true to say that others feel more full of energy, better in health and more responsive to their husbands. The lack of fear of another pregnancy in women who have previously had difficulty in controlling their fertility, the absence of the necessity to prepare for each sexual act, and the complete disassociation between pill-taking and sexuality make this form of contraception very acceptable to many couples.

As compared with oral methods the IUD has advantages in that continuous protection is provided without action by the patient. Moreover, its effect is confined to the uterus and tubes without the widespread metabolic side-effects associated with oestrogen-progestogen preparations. The IUD can therefore be successfully used by many women incapable of using other contraceptive measures.

It is evident that neither barrier nor oral methods are ideal contraceptive procedures. As the findings of the investigation show the IUDs likewise have limitations and disadvantages, but the observations provide some indication of the type of patients and environmental circumstances in which IUDs can most usefully be advised.

The IUD therefore comes close to satisfying some of the requirements of the ideal contraceptive in that its use is dissociated both from the sexual act and upon reliance on the intelligence and motivation of the patient. However, the survey showed that there are three main disadvantages to the use of IUDs; these are: lack of complete efficacy,

the tendency of some patients to expel the device, the occurrence of pain or bleeding severe enough to necessitate removal, or of bleeding which, while not sufficient to require removal may nevertheless cause anaemia. Account must also be taken of the possibility of pelvic inflammation and perforation of the uterus as the direct result of insertion, although neither of these two hazards was encountered in the survey.

Two other factors of some practical importance must also be mentioned. The choice of patients suitable for this method of contraception and the techniques of fitting: both require considerable training and experience. Other methods of contraception are less demanding in this respect. From the patient's point of view she cannot simply discontinue the use of the device if she wishes to become pregnant but must have the device removed by a doctor.

Perhaps the main disadvantage is the lack of complete efficacy, even when the best device is chosen and the patient is apparently suitable. In the investigation the pregnancy rate was 3.5 per 100 woman-years of use. It seems likely that this pregnancy rate would have declined had it been possible to follow up more patients for a longer period, since in other series the pregnancy rate was greatest during the early months of use. This greater rate is probably due to the increased likelihood of expulsion soon after the device is fitted. The rate of 3.5 per 100 woman-years, while much less than that reported for

the sheath and cap - 11.1 and 8.8 per 100 woman-years respectively (International Planned Parenthood Medical Handbook, 1964) - is much greater than for oral contraceptives where the pregnancy rate is less than 1 per 100 woman-years.

Where the prime necessity is complete protection, and providing that the oral method is acceptable to the patient, that there is no medical contraindication and that she can be relied upon to take the pills regularly, oral contraception appears to be the method of choice.

From the personal experience gained during the investigation it appears that failures with IUDs can be reduced to a minimum by ensuring that the patients are properly selected in the first instance. The author's experience has confirmed that IUDs are not suitable for nulliparae. In the investigation the complication rate among nulliparae was more than twice that of parous women.

In avoiding conception the choice of device was also found to be of great importance. A high pregnancy rate was found in parous women fitted with bow 3. A larger bow might possibly have been more effective but even so the pregnancy rate for the larger bows was twice that for the loop. As judged by personal and general experience, Lippes loops are probably the most practical type of IUD. In the investigation most Lippes loops fitted were size C. It may be that the larger size D would be more effective; certainly among the small number of women fitted with loop D no pregnancies occurred during the follow-up, and the complication rate as a whole was less than with other devices.

A further important factor ensuring the utmost efficacy from the IUD is the insertion of the device completely within the uterine cavity with its upper pole lying in close contact across the uterine fundus. Since the patients in the series were all fitted by the author, the observations provided no opportunity to contrast the pregnancy rate observed with that by other operators known to have less experience. However, even with experience it is sometimes difficult to ensure that the device is correctly fitted. Aptitude and training both seem to be important factors in ensuring the greatest ultimate efficacy.

It was evident during the survey that instruction of the patient and a regular check of the device is also necessary if maximum efficacy is to be maintained. In the series about half the expulsions were unnoticed by the patient and were diagnosed at the follow-up visit. Apart from the likelihood of pregnancy, expulsion is in itself a disadvantage and refitting was associated with an increased incidence of complications. In the series the expulsion rate was about 8 per 100 woman-years of use, and the greater incidence in nulliparae indicated that such patients should only be fitted after especially careful consideration. Among the multiparae who repeatedly expelled the loop, the experience of the survey encouraged the view that, provided an IUD is the most suitable form of contraception, a large bow should be used.

As regards the necessity to remove the device because of pain or bleeding, the series suggested that, provided the patients are carefully chosen and the device correctly fitted, pain is uncommon. On the other hand, a striking finding was the inability to predict the occurrence of excessive or persistent menorrhagia after the initial bleeding. It was also clear that the attitude of the patients to menorrhagia varied greatly. To some, heavy periods were a sufficient disadvantage to indicate removal of the device; others with a similar degree of menorrhagia were willing to tolerate this drawback since they found the IUD otherwise suitable and trouble-free. In one patient in the series the IUD was removed because the haemoglobin was less than 60%, and the occurrence of marked anaemia must be regarded as a hazard. Inter-menstrual bleeding requiring removal of the device and investigation occurred on several occasions and represents a further disadvantage.

Perforation of the uterus - except in the cases reported by Lean in Singapore - is rare. Perforation should not occur provided due care is exercised in the choice of patient and the time and technique of insertion. In the present series IUDs were not inserted until at least four weeks after an abortion or eight weeks after delivery. There were no known cases of perforation in the series.

Pelvic infection is often considered to be a hazard of the IUD, but the relative frequency of pelvic infection among women with and without intra-uterine devices has never been ascertained, and the extent to which an IUD might introduce or predispose to pelvic infection is a

matter of speculation. The difficulty of determining the place of IUDs in pre-disposing to pelvic infection is well illustrated by the seven cases diagnosed in the present series. In none of these cases did there appear to be an obvious connection between the IUD and the occurrence of infection. On the other hand, in the author's experience pelvic infection is very rare among women using contraceptive measures other than IUDs; even the small incidence of pelvic inflammatory disease in women using IUDs may thus represent a valid increase associated with the device.

Carcinogensis is sometimes mentioned as a long-term hazard of the IUD. The incidence of positive cervical smears in patients who have worn an IUD for months - or even years - appears to be within normally accepted limits. There is no evidence as yet that plastic intra-uterine devices have any carcinogenic effect on the endometrium or their tails upon the cervical epithelium, but it must be remembered that changes of this kind may take many years to develop. It would seem to be good medical practice to take vaginal and cervical smears from all patients before an IUD is fitted and to repeat this test at regular intervals.

The series provided an opportunity to study the practical value of the IUD to women in all social classes. Taking the clinic, private and hospital series together, a similar proportion of patients was found in social class I, II and III. The IUD was found to be of spcial value for women in social class III for whom other methods of contraception

were often unsuitable. The parity in the women in social class III was very considerably more than that in the other two social classes. Clearly the need for contraceptive advice is greatest in women in class III; this is especially so when their environmental background and the lower intelligence and education is taken into account. A much greater proportion of women in social class III (nearly 80%) attended the hospital as compared with about 33% who attended the North Kensington family planning clinic. This difference was due to the fact that most of the women attending the hospital were referred directly from the obstetric department. An important practical aspect of the findings therefore is that to reach the women whose need on social grounds is greatest, family planning clinics should be attached to obstetric departments of hospitals. Isolated family planning clinics are by no means effective in ministering to the needs of patients in social class III.

The analysis made of the country of origin of the patients illustrates a modern aspect of the health services in a large cosmopolitan society. Almost half the patients attending the hospital clinic were from other countries than the United Kingdom. The majority of these were in social class III, the class most likely to have large families and also the class for whom it is most difficult to provide contraceptive advice.

The analysis of social class also illustrates the substantial

differences which exist in the reasons for fitting the IUD. Women in social class III were almost all fitted for medical or medico-social reasons. They seldom attended of their own volition or for the sake of personal convenience. In contrast, most women in social classes I and II attended because they disliked other methods of contraception.

Taking all these considerations into account the results of the investigation when applied to the three groups of women mentioned at the outset of this discussion are as follows:-

1. For women who have no family and wish to postpone pregnancy the IUD has a very limited field of application.

2. For women with one or more children it has a place for those who have tried and disliked other methods of contraception and are prepared to accept the slight risk of failure, and the possibility of complicationsafter these have been explained to them.

3. For women in the third group, i.e. those for whom other methods of contraception are unsuitable for medical or social reasons, the IUD has a very definite place and its widespread use could be of very considerable social importance.

CONCLUSIONS

1. Intra-uterine devices have a valuable, though limited, place in modern contraceptive practice. These devices are the contraceptive of choice for the 'feckless and fertile' who are unlikely to succeed with other methods. For many such patients it represents virtually the only method of contraception likely to be successful; as such it is potentially of considerable social importance.
2. To ensure that as many social class III patients as possible receive advice on contraception it is essential that family planning clinics are attached to the obstetric departments of hospitals.
3. The intra-uterine device is a useful alternative for some parous women who dislike other methods of contraception but it is unsuitable for the majority of nulliparae.
4. Intra-uterine devices with vaginal appendages have many advantages over those without tails and of these Lippes Loops C and D are the most generally useful.
5. The disadvantages are:-
   (a) the lack of complete contraceptive effectiveness;
   (b) the tendency for some women to expel the device;
   (c) the occurrence of menorrhagia which may be severe enough to cause anaemia or necessitate removal of the device;

(d) the possibility of perforation of the uterus, and pelvic inflammatory disease; and

(e) the occasional occurrence of severe pain or collapse during fitting.

6. Intra-uterine devices should only be fitted by doctors with special training and experience in a properly equipped clinic.

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Table 1. Patients according to series and age group

Series	Age group (years)									
	- 20		20-29		30-39		40+		All ages	
	No.	%	No.	%	No.	%	No.	%	No.	%
Clinic	2	0.9	111	51.3	87	40.3	16	7.5	216	100
Private	3	1.7	66	38.9	73	42.9	*28	16.5	170	100
Hospital	-	-	83	54.3	64	41.9	6	3.9	153	100
All patients	5	0.9	260	48.2	224	41.6	50	9.3	539	100

* Two patients over 50 years of age

Table 2. Patients according to series and parity

Series	Parity								Total
	0	1	2	3	4	5	6	7 or more	
Clinic No.	4	32	65	50	31	10	10	*14	216
%	1.9	14.8	30.1	23.1	14.4	4.6	4.6	6.5	100
Private No.	27	25	65	27	18	6	2	-	170
%	15.9	14.7	38.2	15.9	10.6	3.5	1.2		100
Hospital No.	3	14	48	32	27	12	10	7	153
%	10.0	9.2	31.4	20.9	17.6	7.8	6.5	4.6	100
All patients No.	34	71	178	109	76	28	22	21	539
%	6.3	13.2	33.0	20.2	14.1	5.2	4.1	3.9	100

* One patient with 12 children

Table 3. Patients according to series and social class

Series	Social class grouping						Total
	I		II		III		
	No.	%	No.	%	No.	%	
Clinic	51	23.6	92	42.6	73	33.8	216
Private	117	68.8	40	23.5	13	7.7	170
Hospital	4	2.6	30	19.7	119	77.7	153
All patients	172	31.9	162	30.1	205	38.0	539

Table 4 Patients according to parity and social class

Parity	Social class grouping I	II	III	Total No.	%
0	18	12	4	34	6.3
1	33	23	15	71	13.2
2	55	76	47	178	33.2
3	34	33	42	109	20.2
4	25	15	36	76	14.1
5	5	1	22	28	5.2
6	2	2	18	22	4.1
7 and over	-	-	* 21	21	3.9
All patients	172	162	205	539	100.0
%	31.9	30.1	38.0		

* One with 12 children

Table 5 Average number of children in family according to series and social class

Series	Average number of children		
	Social Class		
	I	II	III
Clinic	2.1	2.4	4.6
Private	2.2	1.6	1.6
Hospital	2.0	2.4	3.4
All patients	2.2	2.2	3.8

Table 6. Patients in each series showing country of origin

Country of origin	Clinic %		Private %		Hospital %		All patients %	
United Kingdom	74.1		81.8		57.5		71.8	
Eire	5.1		0.6		13.7		6.1	
Europe	4.2		8.2		11.8		7.6	
Australia	0.5		1.8		-		0.7	
U.S.A.	1.4	85.3	4.7	97.1		83.0	2.1	88.3
West Indies	11.6		0.6		13.1		8.5	
Africa	0.9	12.5	0.6	1.2	1.3	14.4	0.9	9.4
Asia		2.3		1.8		2.6		2.2
No. of patients	216		170		153		539	

Table 7 Reasons for fitting device, according to series

Series	Reasons for fitting (percentage distribution)					Total cases
	Health	Socio-economic	Dislike of or failure with		Other	
			Conventional contraceptives	Oral contraceptives		
Clinic	12.0	17.1	50.5	20.4	-	216
Private	0.6	-	72.4	24.1	2.9	170
Hospital	43.1	42.5	9.8	4.6	-	153
All patients	17.3	18.9	45.8	17.1	0.9	100

Table 8. Reasons for fitting IUDs in Hospital Series (153 patients)

No.	%	
12	7.8	Cardiovascular (Heart disease 7; hypertension 5)
3	1.9	Renal (Chronic nephritis 1, chronic pyelonephritis 2)
5	3.2	Neurological (Severe epilepsy 3; multiple sclerosis 1; Royal Free disease 1)
23	15.0	Psychiatric
13	8.5	Obstetric (Severe pre-eclamptic toxaemia 4; two or more previous Caesarian sections 6; multiple miscarriages, premature or still births 2; Rh. incompatibility 1)
4	2.6	Eugenic (Two microcephalic children 1; two deformed children 1; one child with familial amyotonia congenita 1; one mongol 1)
6	3.9	Other (Systemic lupus erythematosis 1; severe rheumatoid arthritis 1; chronic hepatitis 2; severe asthma 1; previous cervical biopsy for carcinoma in situ 1)
66	43.1	- All medical conditions
65	42.5	Low socio-economic (four or more children 48; less than four children 17)
12	7.8	Previous failure with conventional contraceptive methods
7	4.6	Complications whilst taking oral contraceptives
3	1.9	Cannot be fitted with cap (Repair operation, prolapse)
87	56.9	- All medico-social reasons

Table 9. Type of device according to date in each series

Series	Date	Device							Total
		Loop				Spiral	Bow		
		A	B	C	D		3	5	
Clinic - A	Feb.1964 - May 1965	4	-	117	-	31	18	9	179
Clinic - B	June 1965 - Sept.1965	-	-	37	-	-	-	-	37
Private	May 1964 - Dec.1966	23	4	123	13	1	6	-	170
Hospital	Sept.1965 - Dec.1966	1	2	126	24*	-	-	-	153
All patients		28	6	403	37	32	24	9	539

* 15.7% - see text

Table 10 Type of device according to parity - all series

Parity	Type of device							Total
	Loop				Spiral	Bow		
	A	B	C	D		3	5	
0	27	4	1	-	-	2	-	34
1	1	-	59	1	4	6	-	71
2	-	2	159	3	7	7	-	178
3	-	-	92	2	8	5	2	109
4	-	-	57	11	5	1	2	76
5	-	-	14	7	3	2	2	28
6	-	-	9	9	1	1	2	22
7 & over	-	-	12	4	4	-	1	21
All patients	28	6	403	37	32	24	9	539

Table 11 Complications at fitting according to series

Series	Complications					Total complications	
	None	Syncope severe	Syncope slight	Pain severe	Pain slight	No.	%
Clinic	209	1	1	3	2	7	3.2
Private	151	2	1	4	12	19	11.2
Hospital	149	-	-	3	1	4	2.6
All patients	509 (94.4%)	3 (0.6%)	2 (0.4%)	10 (1.9%)	15 (2.8%)	30	5.6

Table 12 Total months of use according to series and type of device

Device	CLINIC			PRIVATE			HOSPITAL			ALL SERIES		
	patients	mths. of use no.	avge.	patients	mths. of use no.	avge.	patients	mths. of use no.	avge.	patients	mths. of use no.	avge.
Loop A	4	86	21.5	23	199	8.6	1	1	1.0	28	286	10.2
" B	-	-	-	4	26	6.5	2	28	14.0	6	54	9.0
" C	154	2,583	16.8	123	1,673	13.6	126	1,277	10.0	403	5,533	13.7
" D	-	-	-	13	220	16.9	24	257	10.7	37	477	12.9
Spiral	31	439	14.2	1	28	28.0	-	-	-	32	467	14.6
Bow 3	18	409	22.7	6	98	16.3	-	-	-	24	507	21.1
" 5	9	157	17.4	-	-	-	-	-	-	9	157	17.4
All patients	216	3,674	17.0	170	2,244	13.1	153	1,563	10.2	539	7,481	13.9

Table 13 Number of patients examined at intervals after fitting according to series

Series	Period elapsing since fitting (months)						
	-1	1	2-5	6-11	12-17	18-23	24+
Clinic							
No.	216	212	204	187	155	113	92
%	100	98.1	94.4	86.6	71.8	52.3	42.6
Private							
No.	170	158	141	128	93	51	44
%	100	92.9	82.9	75.3	54.7	30.0	25.9
Hospital							
No.	153	137	121	106	72	29	9
%	100	89.5	79.1	69.3	47.0	18.9	5.9
All patients							
No.	539	507	466	421	320	193	145
%	100	94.0	86.4	78.1	59.4	35.8	26.9

Table 14 Pregnancy rate for 100 woman-years of use according to device - all series

Device	Months of use	Pregnancies	
		Number	Rate per 100 woman-years
Loop A	286	2	8.4
" B	54	1	2.2
" C	5,533	16	3.4
" D	477	-	-
Spiral	467	-	-
Bow 3	507	3	7.1
" 5	157	1	7.6
All patients	7,481	23	3.7

Table 15 Pregnancies according to period elapsing after fitting

	Interval between fitting of device and last visit of patient (months)					
	1	2-5	6-11	12-17	18-23	24+
No. of patients examined	507	466	421	320	193	145
No. of pregnancies	2	4	5	4	6	2

Table 16 Pregnancies according to position of device

Position of device	Duration since insertion	
	less than one year	more than one year
In situ	6	10
Expelled	5	-
Not known	-	2

Table 17 Pregnancies according to parity

Parity	Total patients fitted	Total pregnancies	Percentage pregnant
0	34	3	8.9
1	71	1	1.4
2	178	9	5.0
3	109	3	2.7
4	76	5	6.6
5	28	2	7.0
6 and over	43	-	-
All patients	539	23	4.5

Table 18 Details of all pregnancies - Section A - First insertions (23)
Section B - Second insertions (6)

Section A

Case No.	Device	Parity	Months of use	Position of IUD	Outcome and particulars
1	Loop C	2	1	In situ	Fitted 9.9.66 L.M.P. 16.8.66 Miscarriage and expulsion of IUD 14.10 66 (Foetus 8/52
2	Loop C	5	1	In situ	Normal F.T. delivery. Loop expelled with placenta. Refused to have sterilization
3	Bow 3	4	2	In situ	X-ray in pregnancy. Norma. F.T. delivery. Bow expelled with placenta. Puerperal sterilization
5	Loop C	1	4	In vagina	Normal F.T. delivery
6	Loop A	0	5	In vagina	Normal F.T. delivery
7	Loop C	2	5	In situ	Spotting throughout pregnancy. Missed abortion, D & C at 10 weeks. Subsequent normal F.T. delivery
8	Loop C	4 + 1	6	Expelled	Bleeding after primodos. Normal F.T. delivery
9	Loop C	5 + 2	8	In situ	Hysterotomy and sterilization for psychiatric reasons
10	Loop C	2	8	Expelled from vagina after missed period	Normal F.T. delivery

(continued.....

(Section A continued)

Case No.	Device	Parity	Months of use	Position of IUD	Outcome and particulars
11	Loop A	0	8	In situ	Miscarriage, 10/52
12	Loop C	2	9	In vagina	No follow-up
14	Bow 3	2 + 3	12	In situ	Septic abortion: D & C
16	Loop C	2	14	In situ	Normal F.T. delivery
17	Loop C	2	14	In situ	Hysterotomy and sterilization for congenital cardiac disease
19	Loop C	4	17	In situ	Terminated (twins) for psychiatric reasons (privately)
20	Loop C	3 + 3	18	In situ	No follow-up
21	Loop C	3 + 1	19	No report	
22	Bow 5	4	20	In situ	Central placenta praevia. Caesarean section and sterilization
23	Loop B	0 + 1	20	In situ	Vaginal termination (psychiatric)
24	Bow 3	3 + 1	21	No report	
26	Loop C	2	23	In situ	Vaginal termination
27	Loop C	4	24	In situ	Hysterotomy and sterilization; cardiac disease
29	Loop C	2 + 1	25	In situ	Pregnant now

(continued ... Section B ...

Section B

Case No.	Device	Parity	Months of use	Position of IUD	Outcome and particulars
4	Loop D	5 + 1	3	Expelled	Noticed expulsion. Hysterectomy and sterilization. Groin pregnancy. Hypertension
13	Loop C	2	9	In situ	Ectopic pregnancy. IUD removed; re-insertion
15	Loop B	2	12	No report	
18	Loop D	4	15	Expelled	Vaginal termination for eugenic reasons. Refused sterilization
25	Bow 5	4 + 3	22	In situ	L. ectopic pregnancy; bow left in
28	Loop D	6	24	In situ	Pregnant now

Table 19 Outcome of all pregnancies according to position of IUD - first and second insertions

Outcome	Position of IUD						All pregnancies	
	In situ		Expelled		Not known			
	First ins.	Second ins.	First ins.	Second ins.	First ins.	Second ins.	First ins.	Second ins.
Normal F.T. delivery	2	-	1	-	-	-	3	-
Caesarean section	1	-	-	-	-	-	1	-
Spontaneous miscarriage	4	-	-	-	-	-	4	-
Vaginal termination	3	-	1	1	-	-	3	1
Hysterotomy and sterilization	3	-	-	1	-	-	3	1
Ectopic	-	2	-	-	-	-	-	2
Pregnant now	1	1	-	-	-	-	1	1
Lost to follow-up	2	-	4	-	2	1	8	1
Total	16	3	5	2	2	1	23	6

Table 20 Expulsion rate per 100 woman-years of use by device - all series

Device	Months of use	Number	Rate per 100 woman-years
Loop A	286	5	21.1
" B	54	1	2.3
" C	5,533	35	7.6
" D	477	1	2.5
Spiral	467	7	17.9
Bow 3	507	-	-
" 5	157	-	-
All patients	7,481	49	7.9

Table 21 First expulsions according to months of use

	Months of use						Total
	-2	2-5	6-11	12-17	18-23	24+	
Expulsions	13	16	12	7	-	1	49
Patients examined	507	466	421	320	193	145	539
Percentage expelled	2.4	3.4	2.8	2.2	-	0.7	9.1

Table 22 Expulsions and re-insertions - details and outcome

Total first expulsions ... 49	Outcome:	Pregnant	4		
		Patient did not wish re-insertion	11	15	
		Refitted			34
First re-insertions ... 34	Outcome:	Lost to follow-up	6		
		Pregnant - IUD expelled	1		
		Pregnant - IUD position not known	1		
		Ectopic	2		
		Removed for personal reasons ...	1		
		Removed for medical reasons ...	1		
		Expelled - patient did not wish re-insertion ...	1		
		Satisfactory - in situ	14	27	
		Expelled and re-inserted			7
Second re-insertions 7	Outcome:	Lost to follow-up...	1		
		Removed for pregnancy	1		
		Satisfactory - in situ	4	6	
		Expelled and not refitted			1

Summary of last known state of the 49 patients where IUD was expelled

Pregnant	6	
Ectopic	2	
Did not wish re-insertion	13	
Removed for medical reasons	1	
Removed for pregnancy	1	
Removed for personal reasons	1	
Lost to follow-up	7	31
In situ - satisfactory		18

Table 23 Removal rate per 100 woman-years of use by device - all series

Device	Months of use	Number			Rate per H.W.Y		
		Medical	Personal	All	Medical	Personal	All
Loop A	286	5	2	7	21.1	8.5	29.5
" B	54	-	-	-	-	-	-
" C	5,533	39	27	66	8.5	5.9	14.4
" D	477	4	-	4	10.1	-	10.1
Spiral	467	6	3	9	14.8	7.4	22.2
Bow 3	507	3	1	4	7.2	2.4	9.5
" 5	157	1	-	1	7.7	-	7.7
All patients	7,481	58	33	91	9.3	5.3	14.5

Table 24 Removals according to months of use - all series

Reasons for removal	Months of use							Total
	-1	1	2-5	6-11	12-17	18-23	24+	
Medical	8	2	3	16	18	6	5	58
Personal	-	1	5	5	13	4	5	33
No. of patients examined	539	507	466	421	320	193	145	

Table 25 Reasons for removal - all series, all devices

(a) Medical

Menorrhagia	28	(4 D & C + 1 sterilization)
Spotting	4	(1 hysterectomy for overian cyst)
Pain	10	
Pain + bleeding	6	
Pelvic sepsis	6	(1 laparotomy)
Positive smears	3	(3 D & C and cone biopsies - 1 carcinoma in situ, 1 dysplasia, 1 negative and refitted)
Replaced by larger size	1	
	58	

(b) Personal

Pregnancy desired	25
Patient does not like	6
Husband does not like	1
Dyspareunia	1
	33

Table 26 Details of patients with pelvic inflammatory disease

Case No.	Country of origin	Parity	Device	Months of use	Device removed	Condition and treatment
1	G.B.	2 + 1	Loop C	12	Yes	Tubo ovarian mass; antibiotics in hospital
2	G.B.	6	Bow 5	15	Yes	Recurrent pelvic tenderness; antibiotics in hospital
3	G.B.	1	Loop C	11	Yes	Abscess between bladder and uterus; antibiotics and laparotomy in hospital
4	G.B.	2	Loop C	4	Yes	Endometritis; antibiotic treatment by G.P.
5	U.S.A.	2	Loop C	14	Yes	Tubo ovarian mass; antibiotics in hospital
6	G.B.	2	Loop C	18	No	Pelvic tenderness and bleeding; antibiotic treatment by G.P.
7	G.B.	4	Loop C	18	Yes	Pelvic tenderness and pyrexia; antibiotic treatment in hospital

Table 27 Complication rate per 100 woman-years of use according to device - all series

Device	Pregnancy	Expulsion	*Medical removals	Total	Months of use	Rate 100 woman-years
Loop A	2	5	5	12	286	50.4
" B	1	1	-	2	54	44.5
" C	16	35	39	90	5,533	19.5
" D	-	1	4	5	477	12.6
Spiral	-	7	6	13	467	32.0
Bow 3	3	-	3	6	507	14.3
" 5	1	-	1	2	157	15.3
	23	49	58	130	7,481	20.8

* There were 7 cases of pelvic inflammatory disease, a rate of 1.2 per 100 woman-years. The device was removed in 6 of these cases which are included under medical removals

Table 28 Complications according to months of use - all devices, all series

	Months of use							
	-1	1-	2-5	6-11	12-17	18-23	24+	Total
Pregnancies	-	2	4	5	4	6	2	23
Expulsions	-	13	16	12	7	-	1	49
Removals - medical	8	2	3	16	18	6	5	58
" personal	-	1	5	5	13	4	5	33
Total	8	18	28	38	42	16	13	163
Patients followed up	539	507	466	421	320	193	143	

Table 29 — Removals because pregnancy was desired - details of 25 patients

No.	Age at removal	Parity	Device	Months of use	Months to conceive	Outcome	Re-fitted	Series
1	25	1	Loop C	18	At once	Normal F.T.	Yes 1 yr.	Clinic
2	26	1	"	15	"	" "	" "	"
3	24	1	Bow 6(2nd insert)	22	12	Pregnant		"
4	25	1	Loop C	30	No F.U.			"
5	25	1 + 1	"	20	"			"
6	26	1	"	17	"			"
7	23	1	"	14	"			"
8	29	1	"	13	"			"
9	33	1	"	9	At once	Normal F.T.	Yes 1 yr	Private
10	27	2	"	15	"	" "	" "	"
11	32	3	"	15	"	" "	" "	"
12	26	1	"	9	"	" "	No	"
13	30	-	Loop A	15	6	Misc.11/52	No	"
14	25	1	Bow 3	4	6	Normal F.T.	No	"
15	32	1	Loop C	9	9	" "	No	"

continued....

(Table 29 ..continued)

No.	Age at removal	Parity	Device	Months of use	Months to conceive	Outcome	Re-fitted	Series
16	26	1	Loop C	6	12	Normal F.T.	No	Private
17	27	1	"	8	12	" "	Yes 1 yr.	"
18	36	4	"	24	Not preg. at 1 yr.			"
19	27	1	"	24	Lost to F.U. at 3/12			"
20	25	1	"	22	Lost to F.U. at 3/12			"
21	28	2	"	16	Lost to F.U. at 4/12			"
22	39	2	"	4	No F.U.			"
23	26	1	"	15	No F.U.			"
24	28	2	"	13	Gone abroad			Hospital
25	24	3 + 3	"	19	Lost to F.U. at 3/12			"

Table 30 Removals because pregnancy was desired - all series

Outcome			Subsequent history		
Conceived at once		6	Normal F.T. delivery	10	(re-fitted, 6)
"	within 6 months	2	Miscarriage	1	
"	within one year	4 12	Pregnant now	1	12
Device removed within last 4 months		4			
Not pregnant at one year		1			
Lost to follow-up		8 13			
Total patients seeking pregnancy		25			